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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0098; Product Identifier 2020–NM–011–AD; Amendment 39–19844; AD 2020–03–20]

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 MD–11, MD–11F, and 717–200 airplanes, all Model 737–8 and 737–9 airplanes, all Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes, certain Model 747–400 and 747–400F series airplanes, certain Model 757 and 767 airplanes, and all Model 777 airplanes. This AD requires revising the existing airplane flight manual (AFM) to include a limitation to prohibit operations that require less than 0.3 required navigational performance (RNP) within a specified area for airplanes having a certain multi-mode receiver (MMR) with certain software installed. This AD was prompted by reports of the loss of global positioning system (GPS) data or degraded GPS positional accuracy while using a certain MMR. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 18, 2020.

The FAA must receive comments on this AD by April 3, 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.

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–2020–0098; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–5527) is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: David Sumner, Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3538; email: *david.sumner@faa.gov*.

SUPPLEMENTARY INFORMATION:

Discussion

In December 2019, the FAA received reports of the loss of GPS data or degraded GPS positional accuracy while using a certain MMR with certain software installed. An investigation determined that within a certain region of the world, operational software (OPS), number COL4D–0087–0002, COL4E–0087–0001, COL48–0087–0700, or COL49–0087–0701, if installed on Collins GLU–2100 MMR, part number (P/N) 822–2532–100, could result in a GPS positional error. The affected area occurs in a funnel shaped region of the world that mainly extends +/− 20 degrees on either side of 180 degrees West Longitude, and encompasses the Northern Hemisphere to 10 degrees Latitude in the Southern Hemisphere. When an airplane is within this affected region, the software should map the computed ionospheric pierce point (IPP) to the correct hemisphere, but the software is not doing that. The consequences of the GPS error are:

- An annunciated loss of GPS output, where the Global Navigation Satellite System (GNSS) bus becomes inactive anywhere from a few seconds to up to 40 minutes.
- Un-annunciated reduced positional accuracy in the affected region when the Satellite-Based Augmentation System (SBAS) ionosphere corrections are improperly applied. The positional error will be bounded to 0.3 nautical miles, but may not be bounded by the horizontal protection level (HPL) that is output by the GNSS.

This improper mapping within the OPS, if not addressed, could, during a high-precision approach with a GPS error, result in controlled flight into terrain.

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 revising the existing airplane flight manual to include a limitation to prohibit operations that require less than 0.3 RNP within a specified area for airplanes having a certain MMR with certain software installed.

Interim Action

The FAA considers this AD interim action. Collins is currently developing a software update that will further address the unsafe condition identified in this AD. Once this software update is developed, approved, and available, the FAA might consider additional rulemaking.

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.) 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 seeking comment prior to the

rulemaking. Similarly, Section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies foregoing notice and comment prior to adoption of this rule because, as described in the Discussion section of this AD, the loss of GPS data, or degraded GPS positional accuracy, during a high-precision approach with a GPS positional error, could result in controlled flight into terrain. Given the significance of the risk presented by this unsafe condition, it must be immediately addressed.

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, for the reasons stated above, 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.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment. However, 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–2020–0098 and Product Identifier 2020–NM–011–AD at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this final rule. 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 the agency receives about this final rule.

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 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 David Sumner, Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3538; email: *david.sumner@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

Although the FAA estimates the number of airplanes identified in the applicability of this AD as 3,200 airplanes of U.S. registry, the AFM revision specified in this AD is required only for the airplanes having a configuration identified in paragraph (g) of this AD. The FAA estimates that 409 airplanes of U.S. registry are affected by the AFM revision specified in paragraph (g) of this AD.

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
AFM revision	1 work-hour × $85 per hour = $85	$0	$85	$34,765

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):

2020–03–20 The Boeing Company: Amendment 39–19844; Docket No. FAA–2020–0098; Product Identifier 2020–NM–011–AD.

(a) Effective Date

This AD is effective February 18, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company airplanes, certificated in any category, as identified in paragraphs (c)(1) through (9) of this AD.

(1) Model MD–11 and MD–11F airplanes modified by supplemental type certificate (STC) ST01895WI.

(2) Model 717–200 airplanes modified by STC ST04416AT.

(3) All Model 737–8 and 737–9 airplanes.

(4) All Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes.

(5) Model 747–400 and 747–400F series airplanes modified by STC ST01892WI.

(6) Model 757–200, –200PF, –200CB, and –300 series airplanes modified by STC ST04436AT.

(7) Model 767–200, –300, –300F, –400ER, and –2C series airplanes modified by STC ST04436AT or ST01883WI.

(8) All Model 777–200, –200LR, –300, and –300ER series airplanes.

(9) All Model 777F series airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Unsafe Condition

This AD was prompted by reports of the loss of global positioning system (GPS) data or degraded GPS positional accuracy while using a certain multi-mode receiver (MMR). The FAA is issuing this AD to address the loss of GPS data and degraded GPS positional accuracy, which, during a high-precision approach with this GPS error, could result in controlled flight into terrain.

(f) Compliance

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

(g) Airplane Flight Manual (AFM) Revision

For airplanes equipped with Collins GLU–2100 MMR, part number (P/N) 822–2532–100, having any applicable GLU–2100 operational software (OPS) identified in figure 1 to paragraph (g) of this AD installed: At the applicable time specified in paragraphs (g)(1) and (2) of this AD, revise the limitations or certificate limitations section, as applicable, of the existing AFM to include the information specified in figure 2 to paragraph (g) of this AD and revise the procedures or normal procedures section, as applicable, of the existing AFM to include the information specified in figure 3 to paragraph (g) of this AD. This may be done by inserting a copy of figures 2 and 3 to paragraph (g) of this AD into the existing AFM.

(1) For Model 737–8 and 737–9 airplanes: Before further flight.

(2) For all airplanes except Model 737–8 and 737–9 airplanes: Within 7 days after the effective date of this AD.

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Figure 1 to paragraph (g) – *Affected OPS software*

Airplanes	OPS Software Number
Model 777-200, 777-200LR, 777-300, 777-300ER, and 777F series airplanes	COL4D-0087-0002
Model 737-600, 737-700, 737-700C, 737-800, 737-900, and 737-900ER series airplanes; and Model 737-8, and 737-9 airplanes	COL4E-0087-0001
All airplanes	COL48-0087-0700
Model MD-11, MD-11F, and 717-200 airplanes; and Model 737-600, 737-700, 737-700C, 737-800, 737-900, 737-900ER, 747-400F, 747-400, 757-200, 757-200PF, 757-200CB, 757-300, 767-200, 767-300, 767-300F, 767-400ER, 767-2C, 777-200, 777-200LR, 777-300, 777-300ER, and 777F series airplanes	COL49-0087-0701

Figure 2 to paragraph (g) – *AFM – Limitations or Certificate Limitations*

Electronics – Global Landing Unit (GLU)

(Required by AD 2020-03-20)

Operations that require less than 0.3 RNP (For example, 0.1, 0.11, 0.15, etc.) in the region identified below are prohibited with GLU-2100 OPS software number COL4D-0087-0002, COL4E-0087-0001, COL48-0087-0700, or COL49-0087-0701 installed.

Exception: Anchorage (PANC) approach procedures that allow less than RNP 0.3 are authorized provided the instructions outlined in the Electronics – Global Landing Unit Section of Normal Procedures Chapter are followed.

Note: Currently, Fairbanks (PAFA) and Anchorage (PANC) are the only airports in the region with an RNP approach that requires better than 0.3 nmi performance.

Region bounded by the following coordinates:

Latitude Range (degrees)	Longitude Range (degrees)
80 N to 70 N	40 E to 40 W
70 N to 69 N	134.5 E to 134.38 W
69 N to 68 N	134.5 E to 137.28 W
68 N to 67 N	134.5 E to 139.50 W
67 N to 66 N	134.5 E to 141.58 W
66 N to 65 N	134.5 E to 144.23 W
65 N to 64 N	134.5 E to 145.48 W
64 N to 63 N	134.5 E to 146.44 W
63 N to 62 N	134.5 E to 148.33 W
62 N to 61 N	134.5 E to 149.50 W
61 N to 60 N	134.5 E to 150.35 W
60 N to 59 N	134.5 E to 151.00 W
59 N to 58 N	134.5 E to 151.40 W
58 N to 57 N	134.5 E to 152.62 W
57 N to 56 N	134.5 E to 153.42 W
56 N to 30 N	154 E to 154 W
30 N to 5 N	163 E to 163 W
5 N to 10 S	166 E to 166 W
10 S to 15 S	170 E to 170 W

Figure 2 to paragraph (g) – *AFM – Limitations or Certificate Limitations continued*

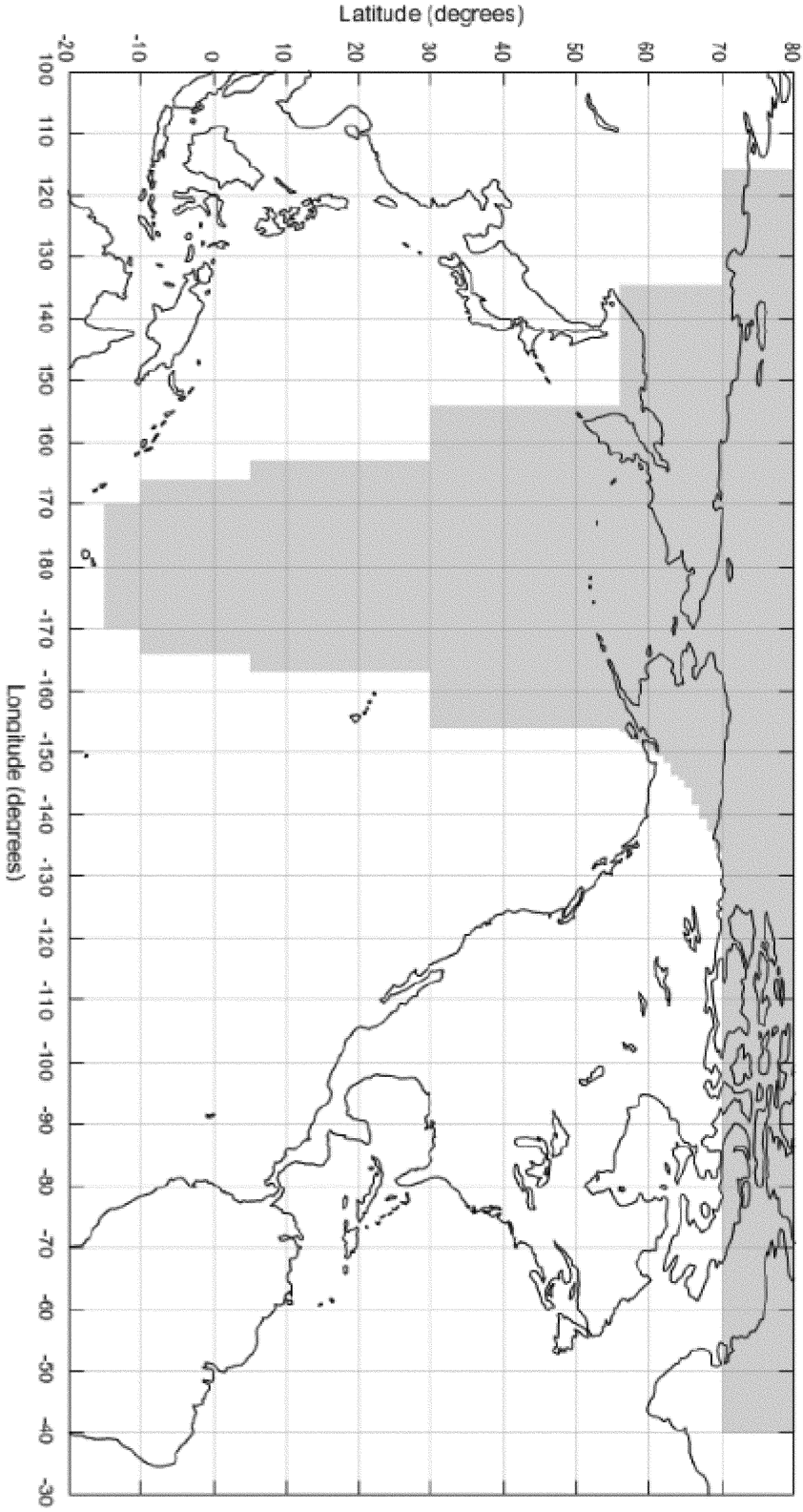

Figure 3 to paragraph (g) – *AFM – Procedures or Normal Procedures*

Electronics – Global Landing Unit (GLU)

(Required by AD 2020-03-20)

To conduct an approach procedure with GLU-2100 OPS software number COL4D-0087-0002, COL4E-0087-0001, COL48-0087-0700, or COL49-0087-0701, installed at Anchorage (PANC) with less than 0.3 RNP, accomplish the following prior to dispatch in accordance with AC 90-101A:

Perform a RNP GPS prediction to ensure the predicted availability of GPS Horizontal Integrity Limit (HIL) is less than MAX HIL for the planned operation time frame at Anchorage (PANC).

MAX HIL = 1.8 (RNP – 0.0726 nm) for LNAV with A/P engaged

MAX HIL = 1.8 (RNP – 0.0926 nm) for LNAV with F/D

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(h) 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 (i) 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.

(i) Related Information

For more information about this AD, contact David Sumner, Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3538; email: *david.sumner@faa.gov.*

(j) Material Incorporated by Reference

None.

Issued on February 12, 2020.

Gaetano A. Sciortino,

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

[FR Doc. 2020–03195 Filed 2–13–20; 11:15 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 744 and 762

[Docket No. 200211–0051]

RIN 0694–AH97

Temporary General License: Extension of Validity

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The U.S. Government has decided to extend through April 1, 2020, the temporary general license to Huawei Technologies Co., Ltd. (Huawei) and one hundred and fourteen of its non-U.S. affiliates on the Entity List. In order to implement this decision, this final rule revises the temporary general license to remove the expiration date of February 16, 2020, and substitute the date of April 1, 2020.

DATES: This rule is effective February 13, 2020, through April 1, 2020, except for amendatory instructions 1 and 3, which are effective February 13, 2020.

FOR FURTHER INFORMATION CONTACT: Director, Office of Exporter Services, Bureau of Industry and Security, Department of Commerce, Phone: (949) 660–0144 or (408) 998–8806 or email your inquiry to: *ECDOEXS@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

As published on May 22, 2019 (84 FR 23468) and extended and amended through a final rule published on August 21, 2019 (84 FR 43487), this temporary general license authorizes certain activities, including those necessary for the continued operations of existing networks and equipment as well as the support of existing mobile services, including cybersecurity research critical to maintaining the integrity and reliability of existing and fully operational networks and equipment. Exporters, reexporters, and transferors are required to maintain certifications and other records, to be made available when requested by BIS, regarding their use of the temporary general license. The expiration date was again updated through February 16, 2020 (84 FR 64018, Nov. 20, 2019).

As published on May 22, 2019 (84 FR 22961), and as revised and clarified by a final rule published on August 21, 2019 (84 FR 43493), any exports, reexports, or in-country transfers of items subject to the EAR to any of the listed Huawei entities as of the effective date they were added to the Entity List continue to require a license, with the exception of transactions explicitly authorized by the temporary general license and eligible for export, reexport, or transfer (in-country) prior to May 16, 2019 without a license or under a license exception. License applications will continue to be reviewed under a presumption of denial, as stated in the Entity List entries for the listed Huawei

entities. No persons are relieved of other obligations under the EAR, including but not limited to licensing requirements to the People's Republic of China (PRC or China) or other destinations and the requirements of part 744 of the EAR. The temporary general license also does not authorize any activities or transactions involving Country Group E countries (*i.e.,* Cuba, Iran, North Korea, Sudan, and Syria) or foreign nationals.

Extension of validity

At this time, the U.S. Government has decided to extend the temporary general license until April 1, 2020. In order to implement this U.S. Government decision, this final rule revises the temporary general license to remove the date of February 16, 2020 and substitute the date of April 1, 2020 in the introductory text in paragraph (b)(1) of the temporary general license and in the introductory text of paragraph (c) of Supplement No. 7 to part 744.

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4801–4852). ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule. As set forth in Section 1768 of ECRA, all delegations, rules, regulations, orders, determinations, licenses, or other forms of administrative action that were made, issued, conducted, or allowed to become effective under the Export Administration Act of 1979 (previously, 50 U.S.C. 4601 *et seq.*) (as in effect prior to August 13, 2018 and as continued in effect pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*)) or the Export Administration Regulations, and were in effect as of August 13, 2018, shall continue in effect according to their terms until modified, superseded, set aside, or revoked under the authority of ECRA.

Rulemaking Requirements

1. 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, 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. This rule has been determined to be not significant for purposes of Executive Order 12866. This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to or be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications, and carries a burden estimate of 42.5 minutes for a manual or electronic submission. Total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to increase as a result of this rule. You may send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget (OMB), by email to *Jasmeet_K._Seehra@omb.eop.gov,* or by fax to (202) 395–7285.

3. This rule does not contain policies with federalism implications as that term is defined in Executive Order 13132.

4. Pursuant to section 1762 of ECRA, this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date.

5. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

List of Subjects

15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Part 762

Administrative practice and procedure, Business and industry, Confidential business information, Exports, Reporting and recordkeeping requirements.

Accordingly, parts 744 and 762 of the Export Administration Regulations (15 CFR parts 730 through 774) is amended as follows:

PART 744—[AMENDED]

■ 1. The authority citation for 15 CFR part 744 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of September 19, 2019, 83 FR 49633 (September 20, 2019); Notice of November 12, 2019, 84 FR 61817 (November 13, 2019).

■ 2. Supplement No. 7 to part 744 is added to read as follows:

Supplement No. 7 to Part 744—Temporary General License

Notwithstanding the requirements and other provisions of Supplement No. 4 to this part, which became effective as to Huawei Technologies Co., Ltd. (Huawei), Shenzhen, Guangdong, China on May 16, 2019, and its non-U.S. affiliates listed in Supplement No. 4 to this part on, as applicable, May 16, 2019 or August 19, 2019, the licensing and other requirements in the EAR as of May 15, 2019, are restored in part as of May 20, 2019, and through April 1, 2020, pertaining to exports, reexports, and transfers (in-country) of items subject to the EAR to any of the listed Huawei entities. The licensing and other policies of the EAR that were in effect as of May 15, 2019, are available to export, reexport, or transfer (in-country) such items to the listed Huawei entities if the transaction meets the conditions of paragraph (b) of this supplement, is limited in scope to one or more of the activities described in paragraphs (c)(1) through (3) of this supplement, and if the transaction parties satisfy the requirements of paragraph (d)(1) of this supplement and, if applicable, paragraph (d)(2) of this supplement. Thus, for example, the authority of NLR or a License Exception that was available as of May 15, 2019, may be used in connection with a transaction as per this temporary general license.

(a) *Identification of non-U.S. affiliates.* The non-U.S. affiliates to whom the licensing and other

requirements of the EAR are restored as described herein are those Huawei entities and affiliates added to the Entity List through the **Federal Register** documents listed in paragraphs (a)(1) and (2) of this supplement:

(1) Addition of Entities to the Entity List, published on 5/21/19.

(2) Non-U.S. affiliates of Huawei added to the Entity List on August 19, 2019.

(b) *Conditions for use of temporary general license.* Use of this temporary general license is subject to the following conditions:

(1) This temporary general license is effective from May 20, 2019, through April 1, 2020.

(2) This temporary general license does not resolve persons of other obligations under the EAR, including but not limited to licensing requirements to the People's Republic of China or elsewhere and/or the requirements of part 744 of the EAR. This authorization does not authorize any activities or transactions involving Country Group E countries (*i.e.,* Cuba, Iran, North Korea, Sudan and Syria) or persons.

(3) With the exception of those explicitly authorized in this temporary general license, exports, reexports, transfers (in-country) continue to require a license pursuant to the licensing policy described on the Entity List and license applications will be reviewed under the license review policy for that entry.

(c) *Authorized transactions.* This temporary general license allows, from May 20, 2019, through April 1, 2020, the following:

(1) *Continued operation of existing networks and equipment.* BIS authorizes, subject to other provisions of the EAR, engagement in transactions necessary to maintain and support existing and currently 'fully operational network' and equipment, including software for bug fixes, security vulnerability patches, and other changes to existing versions of the software, subject to legally binding contracts and agreements executed between Huawei, or one of its listed non-U.S. affiliates, and 'third parties' on or before May 16, 2019. Such transactions may not enhance the functional capacities of the original software or equipment.

(i) *Exclusions.* (A) The authorization under paragraph (c)(1) of this supplement extends only to activities such as patching networks and network infrastructure equipment, not end-devices such as general-purpose computing devices that would not be considered to be part of an existing and 'fully operational network.' Paragraph (c)(1) of this supplement does not authorize support for equipment that is not directly related to the support and maintenance of the network.

(B) The provision of the temporary general license under paragraph (c)(1) of this supplement does not authorize transfers of equipment for general business purposes or for activities that are not in direct support of an existing and 'fully operational network' (*e.g.,* semiconductor production equipment).

(ii) [Reserved]

Note 1 to paragraph (c)(1): The term 'third parties' in paragraph (c)(1) of this supplement and the term 'third party' in Notes 2 and 3 to paragraph (c)(1) refer to a party that is not Huawei, one of its listed non-U.S. affiliates, or the exporter, reexporter, or transferor, but rather an organization such as a telecommunications service provider.

Note 2 to paragraph (c)(1): The term 'fully operational network' in paragraph (c)(1) of this supplement, as well as in paragraph (c)(3) of the supplement, refers to a 'third party' network providing services to the 'third party's' customers.

(2) *Support to existing 'personal consumer electronic devices' and 'Customer Premises Equipment (CPE)'.* BIS authorizes, subject to other provisions of the EAR, engagement in transactions necessary to provide service and support, including software for bug fixes, security vulnerability patches, and other changes to existing versions of the software, to existing Huawei 'personal consumer electronic devices.' Such transactions may not enhance the functional capacities of the original software or equipment. For the purposes of this paragraph (c)(2), the term 'personal consumer electronic devices' is defined as including phones and other personally-owned equipment, such as a tablets, smart watches, and mobile hotspots such as MiFi devices. The authorized transactions under this paragraph (c)(2) include support for personal use of telecommunications hardware known as 'Customer Premises Equipment (CPE),' such as network switches, residential internet gateways, set-top boxes, home networking adapters and other personally-owned equipment that enables consumers to access network communications services and distribute them within their residence or small business. The authorization conferred by this paragraph (c)(2) is limited to models of Huawei 'personal consumer electronic devices' and 'CPE' that were available to the public on or before May 16, 2019.

(3) *Cybersecurity research and vulnerability disclosure.* BIS authorizes, subject to other provisions of the EAR, the disclosure to Huawei and/or to its listed non-U.S. affiliates of information regarding security vulnerabilities in items owned, possessed, or controlled by Huawei or any of its non-U.S. affiliates when related to the process of providing ongoing security research critical to maintaining the integrity and reliability of existing and currently 'fully operational network' and equipment.

(d) *Certification statement.* Prior to making an export, reexport, or transfer (in-country) pursuant to the temporary general license, the exporter, reexporter, or transferor must obtain a certification statement and any additional support documentation needed to substantiate the certification statement from the listed Huawei entity that will receive the item(s), as specified in paragraph (d)(1) of this supplement.

(1) *Certification statement required from Huawei or one of its listed non-U.S. affiliates.* Prior to any export, reexport, or transfer (in-country) under the temporary general license to Huawei or any of its listed non-U.S. affiliates identified in paragraph (a) of this supplement, the exporter, reexporter, or transferor must obtain a certification statement from the entity that will receive the item(s). The temporary general license also requires the party exporting, reexporting, or transferring (in-country) an item ''subject to the EAR'' to obtain, from the listed Huawei entity receiving the item, a certification statement under paragraph (d) of this supplement specifying how the export, reexport, or in-country transfer satisfies the provisions of the temporary general license, including specifying whether the activity or activities that will be supported by the transaction fall within paragraph (c)(1), (2), or (3) of this supplement. In order to substantiate the certification statement for transactions that fall within paragraph (c)(1), the exporter, reexporter, or transferor must obtain documentation from Huawei or one of its listed non-U.S. affiliates showing that there was a legally binding contract or agreement executed between the listed Huawei entity and a 'third party' on or before May 16, 2019. The exporter, reexporter, or transferor and the listed Huawei entity are each responsible for retaining the certification statement and any additional support documentation needed to substantiate the certification statement under paragraph (d). See part 762 of the EAR for record retention requirements. The certification statement must be in writing (which may be conveyed by email), be signed and dated by an individual of sufficient authority to legally bind the listed

entity, and shall provide the information required in paragraphs (d)(1)(i) and (ii) of this supplement and the certifications specified in paragraphs (d)(1)(iii) through (v) of this supplement.

(i) Name of the entity; complete physical address, to include shipping, corporate, and end user addresses, if different (simply listing a post office box is insufficient); telephone number; email address; website (if available); and name and title of individual signing the certification statement;

(ii) A complete list of the item(s), including the applicable Export Control Classification Number(s) or designation (if EAR99) for the item(s) under the EAR, and (for tangible shipments of commodities and software) the quantity or quantities of the item(s) that will be exported, reexported, or transferred under the authority of the temporary general license (this inclusive list may cover multiple exports, reexports, or transfers (in-country) under the temporary general license of the same item(s); see paragraph (d)(2) of this supplement);

(iii) The end-use of the item(s) to be received as an export, reexport, or transfer (in-country) falls within the scope of a specified authorizing paragraph under paragraph (c) of this supplement (a general statement or declaration that the item falls within the scope of paragraph (c) or the scope of the temporary general license will not be sufficient, as the specific authorizing paragraph under paragraph (c) must be identified);

(iv) The entity will comply with the recordkeeping requirements in part 762 of the EAR, including by providing copies of the certification statement and all other export, reexport, or transfer (in-country) records required to be retained in part 762 to any authorized agent, official, or employee of BIS, the U.S. Customs Service, or any other agency of the U.S. Government as required in § 762.7 of the EAR; and

(v) The individual signing the certification statement, on behalf of the consignee identified in paragraph (a) of this supplement, has sufficient authority to legally bind the entity.

(2) *Certification statements may be used for multiple exports, reexports, and transfers (in-country).* Exporters, reexporters, and transferors may rely on the certification statements obtained under paragraph (d)(1) of this supplement for multiple exports, reexports, and transfers (in-country) involving the same item(s) to the same consignee/end-user, provided the information included remains accurate for those additional exports, reexports, and transfers (in-country). If one certification statement is used for multiple exports, reexports, or transfers (in-country) made pursuant to the temporary general license, the exporter, reexporter, and transferor must maintain a log or other similar record that identifies each such export, reexport, and transfer (in-country) against that specific certification statement. The log or other similar record must be retained in accordance with part 762 of the EAR.

PART 762—[AMENDED]

■ 3. The authority citation for part 762 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 4. Section 762.2 is amended by adding paragraph (b)(55) to read as follows:

§ 762.2 Records to be retained.

* * * * *

(b) * * *

(55) Supplement No. 7 to part 744, Temporary General License Certification Statements and logs or other records required, including any additional support documentation needed to substantiate the certification statement, under paragraph (d) of Supplement 7 to part 744 of this chapter.

* * * * *

Dated: February 12, 2020.

Richard E. Ashooh,

Assistant Secretary for Export Administration.

[FR Doc. 2020–03144 Filed 2–13–20; 4:15 pm]

BILLING CODE 3510–33–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9891]

RIN 1545–BM95

Transfers of Certain Property by U.S. Persons to Partnerships With Related Foreign Partners; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations; correction.

SUMMARY: This document contains a correction to final regulations (T.D. 9891) that were published in the **Federal Register** on Thursday, January 23, 2020. Treasury Decision 9891 contains final regulations that provide guidance applicable to transfers of appreciated property by U.S. persons to partnerships with foreign partners related to the transferor.

DATES:

Effective date: These regulations are effective February 18, 2020 and applicable January 23, 2020.

Applicability dates: For dates of applicability, see § 1.721(c)–6.

FOR FURTHER INFORMATION CONTACT: Chadwick Rowland, (202) 317–6937 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9891) that are the subject of this correction are issued under section 721 of the Internal Revenue Code.

Need for Correction

As published, the final regulations (TD 9891), contains errors that may prove to be misleading and are in need of clarification.

Correction to Publication

Accordingly, the final regulations (TD 9891), that are the subject of FR Doc. 2020–00383, in the issue of January 23, 2020 (85 FR 3833), are corrected as follows:

■ 1. On page 3834, in the third column, in the second and third sentence of the second full paragraph, ''PRS1 wholly owns a domestic corporation (UST). In Year 1, UST forms a new partnership (PRS2); as part of the formation, UST contributes section 721(c) property (as defined in § 1.721(c)–1(b)(15)) in return for a 90 percent interest in PRS2's capital and profits, and a U.S. individual (unrelated to UST) contributes cash in return for the remaining interest in PRS2's capital and profits.'' is corrected to read ''PRS1 wholly owns a domestic corporation (UST) and holds 90 percent of the interests in a lower tier partnership's (PRS2) capital and profits. In Year 1, UST and PRS2 form a new partnership (PRS3); as part of the formation, UST contributes section 721(c) property (as defined in § 1.721(c)–1(b)(15)) in return for a 90 percent interest in PRS3's capital and profits, and a U.S. individual (unrelated to UST) contributes cash in return for the remaining interest in PRS3's capital and profits''.

■ 2. On page 3834, in the third column, the second line of the fourth partial paragraph, ''PRS2'' is corrected to read ''PRS3''.

■ 3. On page 3835, in the first column, the second line from the bottom of the first full paragraph, ''consequence, PRS2'' is corrected to read ''consequence, PRS3''.

■ 4. On page 3835, in the third column, the third line from the bottom of the page, ''filed before March 17'' is corrected to read ''filed before July 17.''

Martin V. Franks,

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

[FR Doc. 2020–02654 Filed 2–14–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9891]

RIN 1545–BM95

Transfers of Certain Property by U.S. Persons to Partnerships With Related Foreign Partners; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to final regulations (T.D. 9891) that were published in the **Federal Register** on Thursday, January 23, 2020. Treasury Decision 9891 contains final regulations that provide guidance applicable to transfers of appreciated property by U.S. persons to partnerships with foreign partners related to the transferor.

DATES:

Effective date: These regulations are effective February 18, 2020 and applicable January 23, 2020.

Applicability dates: For dates of applicability, see § 1.721(c)–6.

FOR FURTHER INFORMATION CONTACT: Chadwick Rowland, (202) 317–6937 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9891) that are the subject of this correction are issued under section 721 of the Internal Revenue Code.

Need for Correction

As published, January 23, 2020 (85 FR 3833), the final regulations (TD 9891) contain an error that needs to be corrected.

List of Subjects in 26 CFR Part 1

Income taxes, reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following corrected amendment:

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

§ 1.721(c)–6 [Amended]

■ **Par. 2.** Section 1.721(c)–6(g)(3)(ii) is amended by removing the date ''March 17, 2020'' and adding the date ''July 17, 2020,'' in its place.

Martin V. Franks,

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

[FR Doc. 2020–02653 Filed 2–14–20; 8:45 am]

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1904, 1910, 1915, 1918, and 1926

[Docket No. OSHA–2015–0012]

RIN 1218–AD12

OSHA Standards and Regulations; Corrections

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Final rule; correcting amendments.

SUMMARY: In this rule OSHA is correcting typographical errors, including extraneous or omitted materials and inaccurate graphics, in 27 OSHA standards and regulations. These revisions do not affect the substantive requirements or coverage of the standards, do not modify or revoke existing rights or obligations, and do not establish new rights or obligations. The purpose of these correcting amendments is to reduce regulatory burdens by correcting the inaccuracies in regulatory text and graphics. This rule revises standards in recordkeeping, construction, general industry, shipyard employment, and longshoring.

DATES: Effective February 18, 2020.

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ADDRESSES: *Copies of this* ***Federal Register*** *document and news releases:* Electronic copies of these documents are available at OSHA's web page at *http://www.osha.gov.*

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I. Executive Summary

This rule corrects certain minor errors in 27 OSHA standards and regulations in 29 CFR parts 1904, 1910, 1915, 1918, and 1926. The corrections concern the following regulations and standards: (a) Recording and Reporting Injuries and Illnesses Regulations—including: Partial exemptions; annual summary of work-related injuries and illnesses; and definitions; (b) Occupational Safety and Health Standards for General Industry—including: Applicability of standards to employments in territories; definition and requirements for nationally recognized testing laboratories; electrical generation, transmission, and distribution; lead; and cadmium; (c) Occupational Safety and Health Standards for Shipyard Employment—eye and face protection against welding radiation; (d) Safety and Health Regulations for Longshoring—recommended Specific Program Elements for first aid training; and (e) Safety and Health Regulations for Construction—including: General safety and health provisions concerning applicability to employments in territories; lead; hazardous waste operations and emergency response; electrical use of flexible cords and cables; scaffolds; fall protection-roof width determinations; helicopters-hoists-elevators-and-conveyors-personnel hoists; excavation-Appendix A; steel erection-joists tables; metal decking and shear connectors; fall hazard training; underground construction; electric power transmission and distribution definitions; asbestos; cadmium; and cranes and derricks—routine access to underground construction. The corrections revise typographical errors, including extraneous or omitted materials and inaccurate graphics, in the listed standards.

II. Background

From time to time OSHA receives inquiries from inside and outside the agency concerning minor misprinted, technically inaccurate materials. OSHA researches the inaccuracies and potential revisions. Where necessary, the agency undertakes rulemaking to correct the issues. Where revisions are limited to minor corrections and technical amendments, OSHA publishes a document in the **Federal Register** directing the required revisions be made to the codified version of the regulations. This rule details the errors, the revisions, and directs the needed revisions to be made. Revisions are to be made to both electronic and printed versions of the Code of Federal Regulations (CFR). The agency has researched the changes necessary to correct minor misprints in the following five parts of Title 29: Recording and reporting occupational injuries and illnesses (part 1904), Occupational safety and health standards (Part 1910), Occupational safety and health standards for shipyard employment (part 1915), Longshoring safety and health (part 1918), and Construction safety and health (part 1926). The revisions in this rule serve to correct certain minor errors in the 27 OSHA standards and regulations. This rule is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

III. Summary and Explanation

This rule corrects certain minor errors in 27 OSHA standards and regulations, as summarized in the Executive Summary. These corrections revise typographical errors, including extraneous or omitted materials and inaccurate graphics, in the listed standards. A more detailed discussion of each revision follows.

A. Revisions in Recording and Reporting Occupational Injuries and Illnesses (29 CFR Part 1904)

1. Subpart B of 1904—Scope, Partial Exemption in 29 CFR 1904.1

The agency is correcting omissions in the recordkeeping and reporting scope provision, § 1904.1(a)(1). This section refers to the requirement of § 1904.39 that even partially exempt employers must report certain injuries to OSHA. Existing section § 1904.1(a)(1) mirrors prior § 1904.39(a) reporting requirements for all employers. The prior requirement was to report each fatality and each hospitalization of three or more employees. OSHA revised those reporting requirements in the **Federal Register** (79 FR 56130, September 18, 2014), and the revisions became effective January 1, 2015. The revisions to § 1904.39(a) require all employers, even those partially exempted from recording by the § 1904.1 size exemption, to report a fatality, a hospitalization of one or more employees, an employee amputation, or an employee loss of an eye. This correction will place the corresponding language in § 1904.1(a)(1) so that it mirrors the current requirement. The change in this paragraph is not substantive and does not impose new obligations.

2. Subpart D of 1904—Other OSHA Injury and Illness Recordkeeping Requirements, Annual Summary of Work-Related Injuries and Illnesses in 29 CFR 1904.32

OSHA is also correcting a typographical error in the recordkeeping annual summary provision (§ 1904.32(b)(2)(iii)). The error is a faulty reference to § 1904.6(b)(4) describing equivalent forms allowed for recording annual injury/illness summary data. There is no § 1904.6(b)(4). The correct reference is to § 1904.29(b)(4) ''What is an equivalent form?''

3. Subpart G of 1904—Definitions, in 29 CFR 1904.46

OSHA is also updating § 1904.46 Definitions to correct a typographic omission. The agency revised a longstanding reference to the outdated 1987 Standard Industry Classification (SIC code) manual in 29 CFR 1904.2(b) (79 FR 56130, 56186 (September 18, 2014)). The document replaced the SIC code with the modern North American Industry Classification System-2007 code (NAICS). However, the corresponding replacement of SIC code with NAICS code in the § 1904.46 definition of Establishment at paragraph (1)(iii) did not occur. This rule makes that correction.

B. Revisions in Occupational Safety and Health Standards (29 CFR Part 1910)

1. Subpart A—General, Applicability of Standards in 29 CFR 1910.5

In § 1910.5, OSHA is correcting obsolete regulatory text, which, in addition to any State, the District of Columbia, and U.S. territories, applies OSHA standards to two territories that no longer exist: Trust Territory of the Pacific Islands and the Canal Zone. Section 29 CFR 1910.5(a) corrections will replace the reference to the Trust Territory of the Pacific Island with the Commonwealth of the Northern Mariana Islands and remove the reference to the Canal Zone.

2. Subpart A—General, Definition and Requirements for a Nationally Recognized Testing Laboratory in 29 CFR 1910.7

In Appendix A to § 1910.7 OSHA is correcting a typographical error for the Recognition Process for Nationally Recognized Testing Laboratories (NRTLs). Appendix A, section ''*I. Procedures for Initial OSHA Recognition*'' currently includes sections ''A. Applications,'' ''B. Review and Decision Process; Issuance or Renewal,'' and ''c. *Terms and Conditions of Recognition.*'' In order to eliminate confusion, the existing c title must conform to those of ''A.'' and ''B.'' As it exists, section ''c. *Terms and Conditions of Recognition*'' follows a similarly formatted paragraph B(7)(e),''*Review of final decision,*'' which is the last paragraph of ''B. Review and Decision Process; Issuance or Renewal.'' Existing paragraph ''c'' introduces its own topic, ''Terms and Conditions of Recognition,'' which is corrected to the same format as the A and B titles. Due to the change in the heading, OSHA is also renumbering current c. (1), (2), (3), and (4) to (1)(a), (b), (c), and (d). OSHA is also removing the outdated current paragraph c.(5), *Temporary Recognition of Certain NRTLs,* as the period of temporary recognition ended in 1993 and the two NRTLs listed in the paragraph now have regular NRTL recognition.

3. Subpart R—Special Industries, Electric Power Generation, Transmission, and Distribution in 29 CFR 1910.269

In § 1910.269(x), this rule corrects an outdated reference in the fifth definition of Hazardous Atmosphere to ''Material Safety Data Sheets.'' Due to the global harmonization of Hazard Communications standards, OSHA changed ''Material Safety Data Sheets'' (MSDS) to ''Safety Data Sheet'' (SDS) at 77 FR 17574, 17577 (March 26, 2012).

4. Subpart Z—Toxic and Hazardous Substances, Lead in 29 CFR 1910.1025

OSHA is also correcting a misprinted reference to § 1910.1025(e)(6) in § 1910.1025(e)(3)(ii)(G). In 1995, OSHA removed § 1910.1025(e)(4) and renumbered paragraph (e)(5) as (e)(4) and paragraph (e)(6) as (e)(5) (60 FR 52856, 52858, October 11, 1995). At that time, the reference to paragraph (e)(6) in § 1910.1025(e)(3)(ii)(G) should have been changed to (e)(5) but was not changed. This final rule is correcting the

reference in § 1910.1025(e)(3)(ii)(G) to paragraph (e)(5).

5. Subpart Z—Toxic and Hazardous Substances, Cadmium in 29 CFR 1910.1027

OSHA is removing § 1910.1027(n)(6), which requires medical records to be transferred to the National Institute for Occupational Safety and Health (NIOSH) if the employer goes out of business and does not have a successor employer or other organization designated to receive the records. In the Standards Improvement Project Phase III (SIP–III) rulemaking, OSHA explained that NIOSH found these records were not valuable for research and that the cost of storing the records could not be justified. OSHA then removed the transfer of records requirement from 18 health standards in 29 CFR parts 1910, 1915 and 1926, and in § 1910.1020 itself, but the cadmium standard was inadvertently overlooked (76 FR 33590, 33598, June 8, 2011). OSHA is now making that update in the general industry cadmium standard.

C. Revisions for Occupational Safety and Health Standards for Shipyard Employment (29 CFR 1915)

Subpart I—Personal Protective Equipment (PPE), Eye and Face Protection in 29 CFR 1915.153.

In § 1915.153, this rule corrects format errors in Table I–1—Filter Lenses for Protection Against Radiant Energy by reformatting the table so that the values for ''Operations,'' ''Electrode size,'' ''Arc current,'' and ''Minimum protective shade'' correspond with each other correctly.

D. Revisions to Safety and Health Regulations for Longshoring (29 CFR Part 1918)

Appendix V to Part 1918—Basic Elements of a First Aid Training Program (Non-Mandatory), Specific Program Elements (A)(3) Poisoning

In Non-mandatory Appendix V, Basic Elements of a First Aid Training Program, to 29 CFR 1918, Specific Program Elements paragraph (A)(3), OSHA is updating ''Materials Safety Data Sheet (MSDS)'' to the current terminology ''Safety Data Sheet (SDS).''

E. Revisions to Safety and Health Regulations for Construction (29 CFR Part 1926)

1. Subpart C—General Safety and Health Provisions, General Safety and Health provisions in 29 CFR 1926.20

At § 1926.20(c), General safety and health provisions for construction, this rule corrects the list of territories to which OSHA construction standards apply. The territories are the same as the ones listed in § 1910.5(a) above, as modified by this rule.

2. Subpart D—Occupational Health and Environmental Conditions, Lead in 29 CFR 1926.62

In § 1926.62, the lead standard for construction, OSHA is correcting paragraphs 1926.62(d)(2)(iii) and (iv) by replacing the existing outdated references to ''Table 1 of this section'' with the correct references to ''paragraph (f) of this section.'' Table 1 no longer exists (71 FR 50122, 50191 (August 24, 2006)). Respirator selection must be conducted in accordance with 29 CFR 1910.134(d)(3)(i)(A), as required by § 1926.62(f)(3).

In § 1926.62(d)(3)(iii) and (d)(4)(ii), OSHA is replacing existing misprints referencing ''(d)(10) of this section'' with correct references to ''(d)(9) of this section,'' which addresses the accuracy of measurement required by paragraphs (d)(3)(iii) and (d)(4)(ii). There is no paragraph (d)(10).

In § 1926.62, Appendix B, Section IV—Paragraph (F), OSHA is replacing the outdated reference to Table 1 with the correct reference to § 1926.62(f)(3) of this section for selecting respirators as explained above regarding § 1926.62(d)(2)(iii) and (iv).

3. Subpart D—Occupational Health and Environmental Conditions, Hazardous Waste Operations and Emergency Response in 29 CFR 1926.65

In § 1926.65(a)(2)(i) of Hazardous waste operations and emergency response, OSHA is correcting a misprinted reference to § 1926.20(e)(1). There is no § 1926.20(e)(1); the correct reference, § 1926.20(e), was added in 1993 (58 FR 35076, 35078 (June 30, 1993)).

In § 1926.65(g)(2), OSHA is correcting the outdated acronym ''MSDS'' and term ''Material Safety Data Sheet.'' Due to the global harmonization of Hazard Communications standards OSHA changed these terms to ''SDS'' and ''Safety Data Sheet'' (77 FR 17574, 17577 (March 26, 2012)).

In § 1926.65(l)(3)(vi) and (p)(8)(iv)(E), OSHA is removing misprinted references to § 1926.159. OSHA had imported regulatory text for §§ 1926.97, 1926.98, and 1926.156–1926.159 in error from part 1910 fire protection standards. The 1910 standards, however, were expressly limited in scope and did not cover construction. OSHA corrected the improper incorporation by removing the sections from part 1926, including § 1926.159, in 1996 (61 FR 31427, 31429, 31432 (June 20, 1996)).

In § 1926.65(q)(3)(iii), OSHA is removing a misprinted reference to § 1926.97, for the reason explained in the prior paragraph. The particular text in former § 1926.97 concerned protective clothing for fire brigades. After § 1926.97 was removed (61 FR 31427, 31432 (June 20, 1996)), OSHA later revived § 1926.97 as an unrelated electrical personal protective equipment standard (79 FR 20316, 20693 (April 11, 2014)).

In paragraph 5.1 of Section B in Appendix A to 29 CFR 1926.65, OSHA is correcting an outdated reference of MSDS to SDS and Safety Data Sheet as explained above regarding § 1926.65(g)(2).

4. Subpart K—Electrical, Wiring Methods, Components, and Equipment for General Use in 29 CFR 1926.405

In § 1926.405(g)(1)(iii)(C), OSHA is correcting a misprinted reference to a nonexistent § 1926.405(a)(2)(ii)(1). The correct reference is to § 1926.405(a)(2)(ii)(I), which allows the use of flexible cords and cables through pinch points during construction work if protection is provided to avoid damage.

5. Subpart L—Scaffolds, Additional Requirements Applicable to Specific Types of Scaffolds in 29 CFR 1926.452

In § 1926.452(a)(3), in the Scaffolds standards, OSHA is correcting a pole scaffold metric conversion by replacing the inaccurate conversion of 50 pounds to 222 kilograms. The accurate rounded conversion number is 22.7 kilograms.

In § 1926.452(w)(6)(ii), OSHA is correcting a mobile scaffold reference by replacing the existing misprinted reference to paragraph (x) (Repair bracket scaffolds) of 29 CFR part 1926 subpart L appendix A. The correct reference is to paragraph 2.(w) (Mobile scaffolds) of the same appendix.

Also in § 1926.452(w)(6)(ii), OSHA is removing the misprinted parenthetical phrase ''(ANSI/SIA A92.5 and A92.6)''. The A92.5 standard applies to boom-supported elevating work platforms, and A92.6 applies to self-propelled elevating work platforms.

6. Subpart L—Scaffolds, Appendix E to Subpart L, Drawings and Illustrations

In (Non-mandatory) appendix E of 29 CFR subpart L, OSHA is correcting text and graphic pages, which show maximum vertical tie spacing for scaffolds. The graphics being corrected are titled ''Maximum Vertical Tie Spacing Wider Than 3′–0″ Bases'' and ''Maximum Vertical Tie Spacing 3′–0″

And Narrower Bases.'' Both corrections depict guys, ties, and braces instead of just ties, and the revisions correct captions for attachment points, which must be closest to the required height dimension, whether above or below the exact measurement. Also the revisions correctly depict that connections must be where horizontal scaffold frame members connect inner and outer scaffold legs whether at or closest to the exact height measurement.

7. Subpart M—Fall Protection, Appendix A to Subpart M, Determining Roof Widths

In appendix A to 29 CFR 1926 subpart M, paragraph (1), OSHA is correcting ''Non-mandatory Guidelines for Complying with § 1926.501(b)(10)'' by replacing the misprinted reference to § 1910.501(b)(10) with the correct reference to § 1926.501(b)(10).

Also in appendix A to 29 CFR part 1926 subpart M, OSHA is correcting Example C. Irregularly Shaped Roofs With Rectangular Shaped Sections and Example E. Roofs With Penthouses, Open Courtyards, Additional Floors, Etc., by replacing misprinted references to § 1926.502(b)(10) with the correct reference to § 1926.501(b)(10).

Additionally in subpart M, appendix A, Example C and Example E, OSHA is correcting these titles by centering and conforming the titles with the format used for titles in Examples A, B, D, and F of the appendix. OSHA is also correcting notations in Examples C and E to show that a W symbol means a correct measurement and that a circled ''w'' symbol means an incorrect measurement. The corrections explain a symbol included on the graphics but not included in the explanatory text. The corrections clarify the graphics.

8. Subpart N—Helicopters, Hoists, Elevators, and Conveyors in 29 CFR 1926.552

At § 1926.552(c)(17)(iv), OSHA is replacing misprinted lower case parenthetical italicized paragraph letters (a) through (e) in Personnel hoists with capital parenthetical letters. Preexisting § 1926.552(c)(17)(iv) includes paragraphs (a), (b), (c), (d), and (e). Paragraph 1926.552(c)(17)(iv)(e) is immediately followed by § 1926.552(d) Permanent elevators. This sequence causes confusion. The **Federal Register** Document Drafting Handbook at Table 2–4 requires paragraphs at the (c)(17)(iv) level to be listed with capital parenthetical letters, *i.e.,* (A), (B), (C), (D), and (E). This capitalization would correctly distinguish requirements for material or personnel hoists used only for construction activities from permanent elevators used during construction activities.

9. Subpart P—Excavations, Appendix A to Subpart P, Soil Classification

In paragraph (b) of appendix A to 29 CFR part 1926, subpart P, Excavations, OSHA corrects criteria for *Type C* soil case *(v).* The *Definition* for case *(v)* contains a misprinted, ''or'', which confuses how layered soil systems are interpreted to dip into excavations. The correction, which is consistent with Soil Types A, B, and C in the proposed rule at 52 FR 12288, 12329–30 (April 15, 1987) as well as with Type A and Type B in the Final Rule at 54 FR 45894, 45963 (October 31, 1989), will use ''on.'' ''On'' accurately describes how a layered soil system dips into the excavation. The language is being corrected to explain that a layered system dips into the excavation ''on a slope of four horizontal to one vertical (4H:1V) or steeper.'' OSHA is also correcting an unrelated misspelling of ''minimum'' in paragraph (d)(2)(iii)-*Thumb Penetration* of appendix A.

10. Subpart R—Steel Erection, Structural Steel Assembly in 29 CFR 1926.754

In § 1926.754(c)(2), OSHA is correcting the Steel Erection standard by replacing the current misprinted reference to nonexistent § 1926.760(c)(8) with the correct reference to § 1926.760(c)(7).

11. Subpart R—Steel Erection, Open Web Steel Joists in 29 CFR 1926.757

Additionally, OSHA is correcting Steel Erection joist Tables A and B in § 1926.757(c) (66 FR 5196, 5270 (January 18, 2001)) by revising a typographical footnote error that incorrectly limits an exemption from erection bridging requirements. The footnotes in both Table A, Erection Bridging For Short Span Joists, and Table B, Erection Bridging For Long Span Joists read ''NM=diagonal bolted bridging not mandatory for joists under 40 feet.'' This incorrectly limits the exemption by joist length. The agency discovered the misprinted footnote after it was published and addressed the inaccuracy through question 36(a) in compliance directive CPL 02–01–034 (originally CPL 2–1.34) (March 22, 2002). There is no length limitation for the NM notation. It means not mandatory regardless of joist length.

12. Subpart R—Steel Erection, Training in 29 CFR 1926.761

In § 1926.761(b) *Fall hazard training,* OSHA is correcting misprinted fall protection training requirements. The December 12, 2008 **Federal Register** at page 75589 instructed that § 1926.761(b) be revised. An inadvertent misprint replaced § 1926.761(b) and the subparagraphs with just the regulatory text for paragraph (b) alone, leaving out the subparagraphs (66 FR 5196, 5273 (Jan. 18, 2001)); as amended at (73 FR 75568, 75589 (Dec. 12, 2008)). The correction replaces the inadvertently removed paragraphs (b)(1) through (5). The correction includes the original regulatory text concerning: (1) Hazard recognition, (2) use of fall protection systems, (3) correct procedures for erecting, maintaining fall protection systems, (4) fall prevention procedures, and (5) the fall protection requirements of subpart R.

13. Subpart V—Power Transmission and Distribution, Definitions in 29 CFR 1926.968

In § 1926.968, the definition of *Hazardous atmosphere* includes five examples. The Note to example five contains the outdated term ''Material Safety Data Sheet.'' Due to the global harmonization of Hazard Communications standards, OSHA changed the term to ''Safety Data Sheet (SDS),'' as explained above in the revision to § 1926.65(g)(2)).

14. Subpart Z—Toxic and Hazardous Substances, Asbestos in 29 CFR 1926.1101

At § 1926.1101(e)(4), OSHA is correcting a typographical error in the Asbestos standard by replacing a reference to ''(h)(2) of this section'' with ''(h)(3) of this section.'' For entrance into a regulated area § 1926.1101(e)(4) requires that employees wear respirators selected in accordance with the referenced paragraph. Paragraph (h)(2) requires the employer to implement a respiratory protection program. Paragraph (h)(3) details the criteria that employers must use to select and provide each employee an appropriate respirator for protection against asbestos exposure.

In § 1926.1101(f)(3)(iii), OSHA is removing the redundant use of the word ''respirator''.

At § 1926.1101(g)(7), OSHA is correcting a typographical error by correctly italicizing the section title, *Work Practices and Engineering Controls for Class II work.*

In § 1926.1101(g)(8)(v), OSHA is replacing a misprinted reference to § 1926.1101(g)(8)(iv)(A) through (D) with the correct reference to ''§ 1926.1101(g)(8)(i) through (iv)'' of this section.

In § 1926.1101(n)(2)(iii) and (n)(3)(i) and (iii), OSHA is replacing misprinted

references to § 1910.33 with correct references to § 1910.1020.

At § 1926.1101(p)(1), OSHA is also correcting the Asbestos standard by deleting the reference to appendix C of 29 CFR 1926.1101 because the appendix no longer exists. OSHA removed and reserved the appendix when it consolidated respiratory protection requirements for general industry, construction, shipyard, longshoring, and marine terminal workplaces in 29 CFR 1910.134 (see 63 FR 1152, 1298 (January 8, 1998)).

In appendix K to § 1926.1101 paragraph (e) to paragraph 3.1, OSHA is correcting an outdated reference to MSDS with reference to SDS and Safety Data Sheet as discussed above in the similar correction to § 1926.65(g)(2).

15. Subpart Z—Toxic and Hazardous Substances, Cadmium in 29 CFR 1926.1127

In paragraph (d)(1)(i) to § 1926.1127, OSHA is correcting an outdated reference to MSDS with reference to SDS and Safety Data Sheet as discussed above in the similar correction to § 1926.65(g)(2).

In paragraphs (n)(1)(iii) and (n)(3)(iii) of § 1926.1127, OSHA is revising the references to § 1926.33 to more directly refer to § 1910.1020. Section 1910.1020 is the *Access to employee exposure and medical records regulation,* and § 1926.33 is currently a cross-reference to § 1910.1020, so the change is simply to make the reference more direct. Recent rulemakings have used this direct reference to the general industry standard in the construction standards. Above, regarding § 1926.1101(n), OSHA corrected misprinted references to § 1910.1020, and OSHA made the same change in other sections of the construction Asbestos standard in the SIP–III rulemaking (76 FR 33590, 33601, June 8, 2011). Existing § 1926.1127(n)(4)(i) also currently refers directly to § 1910.1020.

OSHA is also removing subparagraph (n)(5), which requires medical records to be transferred to NIOSH if the employer goes out of business and does not have a successor employer or other organization designated to receive the records for the reasons described above regarding the cadmium standard for general industry, § 1910.1027(n)(6).

16. Subpart CC—Cranes and Derricks in Construction, Hoisting Personnel in 29 CFR 1926.1431

In § 1926.1431(a), OSHA is adding a particular work activity, routine employee access to an underground construction worksite via a shaft when hoisted by a crane or derrick, to the list of work activities exempt from an employer's infeasibility demonstration requirement before using equipment to hoist employees. The infeasibility requirement for this activity was removed by changes to § 1926.800(t) ''*Hoisting unique to underground construction*'' (78 FR 23837 (April 23, 2013)).

IV. Agency Considerations

A. Economic Analysis and Regulatory Flexibility Analysis

The revisions will correct minor misprints, omissions, outdated references, and tabular and graphic inaccuracies. This will make the standards easier for employers and workers to understand and follow, as well as improve compliance assistance and enforcement. In addition, the corrections reduce confusion, save time, and thus may save costs.

The corrections and revisions are minor. None of them expand employer obligations or impose new costs. The corrections do not have significant impact on any small employer. Therefore, OSHA has determined that this rulemaking is not a significant rule with respect to Executive Order 12866 and complies with Executive Order 13563. OSHA certifies that this rulemaking will not have a significant economic impact on a substantial number of small entities.

B. Legal Considerations: Exemption from Notice and Comment Procedures

OSHA determined that this rulemaking is not subject to the procedures for public notice and comment specified in Section 4 of the Administrative Procedure Act (5 U.S.C. 553) or Section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(b)). This rulemaking does not affect or change any existing rights or obligations, and no stakeholder is likely to object to them. Therefore, the agency finds good cause, in accordance with 29 CFR 1911.5, that public notice and comment are unnecessary within the meaning of 5 U.S.C. 553(b)(3)(B) and 29 U.S.C. 655(b).

C. Paperwork Reduction Act

After reviewing the rule and associated information collections, OSHA has determined that none of the correcting amendments would create new or revise existing information collections. Table A lists the collections of information affected by the correcting amendments.

TABLE A—AFFECTED COLLECTIONS OF INFORMATION

OMB Control No.	Collection of information
1218–0176 ..	Recordkeeping and Reporting Injuries and Illnesses (29 CFR 1904).
1218–0092 ..	Lead in General Industry Standard (29 CFR 1910.1025).
1218–0185 ..	Cadmium in General Industry Standard (29 CFR 1910.1027).
1218–0134 ..	Asbestos in Construction Standard (29 CFR 1926.1101).

OSHA notes that a Federal agency cannot conduct or sponsor a collection of information unless OMB approves it under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), and the agency displays a currently valid OMB control number. The public need not respond to a collection of information requirement unless the agency displays a currently valid OMB control number, and, notwithstanding any other provision of law, no person shall be subject to a penalty for failing to comply with a collection of information requirement if the requirement does not display a currently valid OMB control number.

D. Federalism

OSHA reviewed the included minor revisions in accordance with the Executive Order on Federalism (Executive Order 13132, 64 FR 43255, August 10, 1999), which requires that Federal agencies, to the extent possible, refrain from limiting State policy options, consult with States prior to taking any actions that would restrict State policy options, and take such actions only when clear constitutional authority exists and the problem is national in scope. Executive Order 13132 provides for preemption of State law only with the expressed consent of Congress. Agencies must limit any such preemption to the extent possible.

Under Section 18 of the OSH Act, Congress expressly provides that States may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards; States that obtain Federal approval for such a plan are referred to as ''State Plan States.'' (29 U.S.C. 667.) Occupational safety and health standards developed by State Plan States must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards.

While OSHA drafted these minor revisions to clarify existing employee protections in every State, Section 18(c)(2) of the OSH Act permits State Plan States and Territories to develop and enforce their own standards, provided the requirements in these standards are at least as safe and healthful as the requirements specified in these corrections to existing standards.

In summary, as described above in Section IV(B) Legal Considerations, OSHA determined that this rule does not affect or change any existing rights or obligations, and no stakeholder is likely to object to them; therefore, in States with OSHA-approved State Plans, this rulemaking would not significantly limit State policy options.

E. State Plans

When Federal OSHA promulgates a new standard or a more stringent amendment to an existing standard, the 28 States and U.S. Territories with their own OSHA-approved occupational safety and health plans (State Plans) must amend their standards to reflect the new standard or amendment. Optionally they may show OSHA why such action is unnecessary (*e.g.,* because an existing State standard covering this area is already ''at least as effective'' as the new Federal standard or amendment (29 CFR 1953.5(a)). Since this rule publishes minor corrections to existing standards, it is unlikely that any State Plan needs to draft a new standard or amendment to an existing standard. When OSHA promulgates technical amendments or minor corrections that do not impose additional or more stringent requirements than the existing standards, State Plans are not required to amend or correct their standards, although OSHA may encourage them to do so.

The 28 States and territories with OSHA-approved State Plans are: Alaska, Arizona, California, Connecticut, Hawaii, Illinois, Indiana, Iowa, Kentucky, Maine, Maryland, Michigan, Minnesota, Nevada, New Mexico, New Jersey, New York, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. Of those Connecticut, Illinois, Maine, New Jersey, New York, and the Virgin Islands have OSHA-approved State Plans that apply to State and local government employees only.

OSHA concludes that these minor corrections and technical amendments will clarify existing protections afforded employees while reducing the compliance burden and confusion for employers. Therefore, OSHA urges States and Territories with approved State Plans to make appropriate revisions to their standards.

F. Unfunded Mandates Reform Act of 1995

OSHA reviewed the included minor corrections in accordance with the Unfunded Mandates Reform Act of 1995 (UMRA; 2 U.S.C. 1501 *et seq.*) and Executive Order 12875 (56 FR 58093). As noted under section IV(E) (''State Plans'') of this rule, the agency's standards do not apply to State and local governments except in States that elect voluntarily to adopt a State Plan approved by the agency. Consequently, these corrections and technical amendments, in addition to being minor and not changing substantive protections, do not meet the definition of a ''Federal intergovernmental mandate'' (see Section 421(5) of the UMRA (2 U.S.C. 658(5)). Therefore, for the purposes of the UMRA, the agency certifies that these minor corrections and technical amendments do not mandate that State, local, or tribal governments adopt new, unfunded regulatory obligations, or increase expenditures by the private sector of more than $100 million in any year.

V. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, authorized the preparation of this rule pursuant to Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), 29 CFR part 1911, and Secretary's Order 1–2012 (77 FR 3912).

Signed at Washington, DC.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

Corrections to Standards

For the reasons stated in the preamble of this final rule, the Occupational Safety and Health Administration amends 29 CFR parts 1904, 1910, 1915, 1918, and 1926 as follows:

PART 1904—RECORDING AND REPORTING OCCUPATIONAL INJURIES AND ILLNESSES

■ 1. The authority citation for part 1904 continues to read as follows:

Authority: 29 U.S.C. 657, 658, 660, 666, 669, 673, Secretary of Labor's Order 1–2012 (77 FR 3912, Jan. 25, 2012).

Subpart B—Scope

■ 2. In § 1904.1, revise paragraph (a)(1) to read as follows:

§ 1904.1 Partial exemption for employers with 10 or fewer employees.

(a) * * *

(1) If your company had 10 or fewer employees at all times during the last calendar year, you do not need to keep OSHA injury and illness records unless OSHA or the Bureau of Labor Statistics informs you in writing that you must keep records under § 1904.41 or § 1904.42. However, as required by § 1904.39, all employers covered by the OSH Act must report to OSHA any work-related incident that results in a fatality, the in-patient hospitalization of one or more employees, an employee amputation, or an employee loss of an eye.

* * * * *

Subpart D—Other OSHA Injury and Illness Recordkeeping Requirements

■ 3. In § 1904.32, revise paragraph (b)(2)(iii) to read as follows:

§ 1904.32 Annual summary.

* * * * *

(b) * * *

(2) * * *

(iii) If you are using an equivalent form other than the OSHA 300–A summary form, as permitted under § 1904.29(b)(4), the summary you use must also include the employee access and employer penalty statements found on the OSHA 300–A Summary form.

* * * * *

Subpart G—Definitions

■ 4. In § 1904.46, revise paragraph (1)(iii) in the definition of ''Establishment'' to read as follows:

§ 1904.46 Definitions.

* * * * *

Establishment. * * *

(1) * * *

(iii) No one industry description in the North American Industry Classification System (2007) codes applies to the joint activities of the establishments; and

* * * * *

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Subpart A—General

■ 5. The authority citation for subpart A continues to read as follows:

Authority: 29 U.S.C. 653, 655, 657; Secretary of Labor's Order Numbers 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31159), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable.

Sections 1910.6, 1910.7, 1910.8 and 1910.9 also issued under 29 CFR 1911. Section 1910.7(f) also issued under 31 U.S.C. 9701, 29 U.S.C. 9a, 5 U.S.C. 553; Public Law 106–113 (113 Stat. 1501A–222); Pub. L. 11–8 and 111–317; and OMB Circular A–25 (dated July 8, 1993) (58 FR 38142, July 15, 1993).

■ 6. In § 1910.5, revise paragraph (a) to read as follows:

§ 1910.5 Applicability of standards.

(a) Except as provided in paragraph (b) of this section, the standards contained in this Part shall apply with respect to employments performed in a workplace in a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, Wake Island, Outer Continental Shelf lands defined in the Outer Continental Shelf Lands Act, and Johnston Island.

* * * * *

■ 7. In § 1910.7, in appendix A, revise section I.c to read as follows:

§ 1910.7 Definition and requirements for a nationally recognized testing laboratory.

* * * * *

Appendix A to § 1910.7—OSHA Recognition Process for Nationally Recognized Testing Laboratories

* * * * *

I. Procedures for Initial OSHA Recognition

* * * * *

C. Terms and Conditions of Recognition

1. The following terms and conditions shall be part of every recognition:

a. *Letter of recognition.* The recognition by OSHA of any NRTL will be evidenced by a letter of recognition from OSHA. The letter will provide the specific details of the scope of the OSHA recognition, including the specific equipment or materials for which OSHA recognition has been granted, as well as any specific conditions imposed by OSHA.

b. *Period of recognition.* The recognition by OSHA of each NRTL will be valid for five years, unless terminated before the expiration of the period. The dates of the period of recognition will be stated in the recognition letter.

c. *Constancy in operations.* The recognized NRTL shall continue to satisfy all the requirements or limitations in the letter of recognition during the period of recognition.

d. *Accurate publicity.* The OSHA-recognized NRTL shall not engage in or permit others to engage in misrepresentation of the scope or conditions of its recognition.

2. [Reserved]

* * * * *

Subpart R—Special Industries

■ 8. The authority citation for subpart R continues to read as follows:

Authority: 29 U.S.C. 653, 655, 657; Secretary of Labor's Order Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 5–2007 (72 FR 31159), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

■ 9. In § 1910.269, in paragraph (x), revise the note following paragraph (5) of the definition of ''hazardous atmosphere'' to read as follows:

§ 1910.269 Electric power generation, transmission, and distribution.

* * * * *

(x) * * *

Hazardous atmosphere. * * *

(5) * * *

Note to the definition of ''hazardous atmosphere'' (5): For air contaminants for which the Occupational Safety and Health Administration has not determined a dose or permissible exposure limit, other sources of information, such as Safety Data Sheets (SDS) that comply with the Hazard Communication Standard, § 1910.1200, published information, and internal documents can provide guidance in establishing acceptable atmospheric conditions.

* * * * *

Subpart Z—Toxic and Hazardous Substances

■ 10. The authority citation for subpart Z continues to read as follows:

Authority: 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), 29 CFR part 1911; and 5 U.S.C. 553, as applicable.

Section 1910.1030 also issued under Pub. L. 106–430, 114 Stat. 1901.

Section 1910.1201 also issued under 49 U.S.C. 5101 *et seq.*

■ 11. In § 1910.1025, revise paragraph (e)(3)(ii)(G) to read as follows:

§ 1910.1025 Lead.

* * * * *

(e) * * *

(3) * * *

(ii) * * *

(G) An administrative control schedule required by paragraph (e)(5) of this section, if applicable;

* * * * *

§ 1910.1027 [Amended]

■ 12. In § 1910.1027, remove paragraph (n)(6).

PART 1915—OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR SHIPYARD EMPLOYMENT

■ 13. The authority citation for part 1915 continues to read:

Authority: 33 U.S.C. 941; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912); 29 CFR part 1911; and 5 U.S.C. 553, as applicable.

Subpart I—Personal Protective Equipment (PPE)

■ 14. In § 1915.153, revise Table I—1 to read as follows:

§ 1915.153 Eye and face protection.

* * * * *

TABLE I–1—FILTER LENSES FOR PROTECTION AGAINST RADIANT ENERGY

Operations	Electrode size 1/32 in	Arc current	Minimum * protective shade
Shielded metal arc welding	Less than 3	Less than 60	7
	3–5	60–160	8
	5–8	160–250	10
	More than 8	250–550	11
Gas metal arc welding and flux cored arc welding.		Less than 60	7
		60–160	10
		160–250	10
		250–500	10
Gas Tungsten arc welding		Less than 50	8
		50–150	8
		150–500	10
Air carbon	(Light)	Less than 500	10

TABLE I–1—FILTER LENSES FOR PROTECTION AGAINST RADIANT ENERGY—Continued

Operations	Electrode size 1/32 in	Arc current	Minimum * protective shade
Arc cutting	(Heavy)	500–1000	11
Plasma arc welding		Less than 20	6
		20–100	8
		100–400	10
		400–800	11
Plasma arc cutting	(light) **	Less than 300	8
	(medium) **	300–400	9
	(heavy) **	400–800	10
Torch brazing			3
Torch soldering			2
Carbon arc welding			14

** These values apply where the actual arc is clearly seen. Lighter filters may be used when the arc is hidden by the workpiece.

FILTER LENSES FOR PROTECTION AGAINST RADIANT ENERGY

Operations	Plate thickness—inches	Plate thickness—mm	Minimum * protective shade
Gas Welding:			
Light	Under 1/8	Under 3.2	4
Medium	1/8 to 1/2	3.2 to 12.7	5
Heavy	Over 1/2	Over 12.7	6
Oxygen cutting:			
Light	Under 1	Under 25	3
Medium	1 to 6	25 to 150	4
Heavy	Over 6	Over 150	5

* As a rule of thumb, start with a shade that is too dark to see the weld zone. Then go to a lighter shade which gives sufficient view of the weld zone without going below the minimum. In oxyfuel gas welding or cutting where the torch produces a high yellow light, it is desirable to use a filter lens that absorbs the yellow or sodium line in the visible light of the (spectrum) operation.

* * * * *

PART 1918—SAFETY AND HEALTH REGULATIONS FOR LONGSHORING

■ 15. The authority citation for part 1918 is revised to read as follows:

Authority: 33 U.S.C. 941; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; and 29 CFR 1911.

Section 1918.90 also issued under 5 U.S.C. 553.

Section 1918.100 also issued under 49 U.S.C. 5101 *et seq.* and 5 U.S.C. 553.

Subpart H—Handling Cargo

■ 16. In appendix V to part 1918 to read as follows:

Appendix V to Part 1918—Basic Elements of a First Aid Training Program (Non-Mandatory)

Note: This appendix is non-mandatory and provides guidelines for small businesses and institutions teaching first aid, as well as for the recipients of first aid training.

General Program Elements

A. Teaching Methods

1. Trainees should develop ''hands on'' skills through the use of manikins and trainee partners during their training.
2. Trainees should be exposed to acute injury and illness settings as well as the appropriate response to those settings through the use of visual aids, such as video tape and slides.
3. Training should include a course workbook which discusses first aid principles and responses to settings that require interventions.
4. Training duration should allow enough time for particular emphasis on situations likely to be encountered in particular workplaces.
5. An emphasis on quick response to first aid situations should be incorporated throughout the program.

B. Principles of Responding to a Health Emergency

The training program should include instruction in:

1. Injury and acute illness as a health problem.
2. Interactions with the local emergency medical services system. Trainees have the responsibility for maintaining a current list of emergency telephone numbers (police, fire, ambulance, poison control) easily accessible to all employees.
3. The principles of triage.
4. The legal aspects of providing first aid services.

C. Methods of Surveying the Scene and the Victim(s)

The training program should include instruction in:

1. The assessment of scenes that require first aid services including:
   a. General scene safety.
   b. likely event sequence.
   c. rapid estimate of the number of persons injured.
   d. identification of others able to help at the scene.
2. Performing a primary survey of each victim including airway, breathing, and circulation assessments as well as the presence of any bleeding.
3. The techniques and principles of taking a victim's history at the scene of an emergency.
4. Performing a secondary survey of the victim including assessments of vital signs, skin appearance, head and neck, eye, chest, abdomen, back, extremities, and medical alert symbols.

D. Basic Adult Cardiopulmonary Resuscitation (CPR)

Basic adult CPR training should be included in the program. Retesting should occur every year. The training program should include instruction in:

1. Establishing and maintaining adult airway patency.
2. Performing adult breathing resuscitation.

3. Performing adult circulatory resuscitation.
4. Performing choking assessments and appropriate first aid interventions.
5. Resuscitating the drowning victim.

E. Basic First Aid Intervention

Trainees should receive instruction in the principles and performance of:
1. Bandaging of the head, chest, shoulder, arm, leg, wrist, elbow, foot, ankle, fingers, toes, and knee.
2. Splinting of the arm, elbow, clavicle, fingers, hand, forearm, ribs, hip, femur, lower leg, ankle, knee, foot, and toes.
3. Moving and rescuing victims including one and two person lifts, ankle and shoulder pulls, and the blanket pull.

F. Universal Precautions

Trainees should be provided with adequate instruction on the need for and use of universal precautions. This should include:
1. The meaning of universal precautions, which body fluids are considered potentially infectious, and which are regarded as hazardous.
2. The value of universal precautions for infectious diseases such as AIDS and hepatitis B.
3. A copy of OSHA's standard for occupational exposure to bloodborne pathogens or information on how to obtain a copy.
4. The necessity for keeping gloves and other protective equipment readily available and the appropriate use of them.
5. The appropriate tagging and disposal of any sharp item or instrument requiring special disposal measures such as blood soaked material.
6. The appropriate management of blood spills.

G. First Aid Supplies

The first aid provider should be responsible for the type, amount, and maintenance of first aid supplies needed for their particular worksite(s). These supplies need to be stored in a convenient area available for emergency access.

H. Trainee Assessments

Assessment of successful completion of the first aid training program should include instructor observation of acquired skills and written performance assessments. First aid skills and knowledge should be reviewed every three years.

I. Program Update

The training program should be periodically reviewed with current first aid techniques and knowledge. Outdated material should be replaced or removed.

Specific Program Elements

A. Type of Injury Training

1. Shock

Instruction in the principles and first aid intervention in:
a. Shock due to injury.
b. shock due to allergic reactions.
c. the appropriate assessment and first aid treatment of a victim who has fainted.

2. Bleeding

a. The types of bleeding including arterial, venous, capillary, external, and internal.
b. the principles and performance of bleeding control interventions including direct pressure, pressure points, elevation, and pressure bandaging.
c. the assessment and approach to wounds including abrasions, incisions, lacerations, punctures, avulsions, amputations, and crush injuries.
d. the principles of wound care including infection precautions, wounds requiring medical attention, and the need for tetanus prophylaxis.

3. Poisoning

Instruction in the principles and first aid intervention of:
a. Alkali, acid and systemic poisons. In addition, all trainees should know how and when to contact the local Poison Control Center.
b. inhaled poisons including carbon monoxide, carbon dioxide, smoke, and chemical fumes, vapors and gases as well as the importance of assessing the toxic potential of the environment to the rescuer and the need for respirators.
Trainees should be instructed in the acute effect of chemicals utilized in their plants, the location of chemical inventories, Safety Data Sheets (SDS), chemical emergency information, and antidote supplies.
c. topical poisons including poison ivy, poison sumac, poison oak, and insecticides.
d. drugs of abuse including alcohol, narcotics such as heroin and cocaine, tranquilizers, and amphetamines.

4. Burns

Instruction in the principles and first aid intervention of:
a. Assessing the severity of the burn including first degree, second degree, and third degree burns.
b. differentiating between the types of third degree burns (thermal, electrical, and chemical) and their specific interventions. Particular attention should be focused upon chemical burns, and the use of specific chemicals in the workplace which may cause them.

5. Temperature Extremes

Instruction in the principles and first aid intervention of:
a. Exposure to cold including frostbite and hypothermia.
b. exposure to heat including heat cramps, heat exhaustion, and heat stroke.

6. Musculoskeletal Injuries

The training program should include instruction in the principles and first aid intervention in:
a. Open fractures, closed fractures, and splinting.
b. dislocations, especially the methods of joint dislocations of the upper extremity. The importance of differentiating dislocations from fractures.
c. joint sprains.
d. muscle strains, contusions, and cramps.
e. head, neck, back, and spinal injuries.

7. Bites and Stings

Instruction in the principles and first aid intervention in:
a. Human and animal (especially dog and snake) bites.
b. bites and stings from insects (spiders, ticks, scorpions, hornets and wasps). Interventions should include responses to anaphylactic shock; other allergic manifestations; and rabies and tetanus prophylaxis.

8. Medical Emergencies

Instruction in the principles and first aid intervention of:
a. Heart attacks.
b. strokes.
c. asthma attacks.
d. diabetic emergencies including diabetic coma, insulin shock, hyperglycemia, and hypoglycemia.
e. seizures including tonic-clonic and absence seizures. Importance of *not* putting gags in mouth.
f. pregnancy including the appropriate care of any abdominal injury or vaginal bleeding.

9. Confined Spaces

a. The danger of entering a confined space to administer first aid without having the appropriate respiratory protection.
b. if first aid personnel will be required to assist evacuations from confined spaces, additional training will be needed.

B. Site of Injury Training

Instruction in the principles and first aid intervention of injuries to the following sites:

1. Head and Neck

a. Including skull fractures, concussions, and mental status assessments with particular attention to temporary loss of consciousness and the need for referral to a physician.
b. including the appropriate approach to the management of the individual who has suffered a potential neck injury or fracture.

2. Eye

a. Foreign bodies, corneal abrasions and lacerations.
b. chemical burns and the importance of flushing out the eye.
c. the importance of not applying antibiotics without physician supervision.

3. Nose

a. Nose injuries and nose bleeds.

4. Mouth and Teeth

a. Oral injuries, lip and tongue injuries, and broken and removed teeth. The importance of preventing inhalation of blood and teeth.

5. Chest

a. Rib fractures, flail chest, and penetrating wounds.

6. Abdomen

a. Blunt injuries, penetrating injuries, and protruding organs.

7. Hand, Finger, and Foot Injuries

a. Finger/toe nail hematoma, lacerations, splinters, finger nail avulsion, ring removal, and foreign bodies.
b. the importance of identifying amputation care hospitals in the area. When

an amputation occurs, appropriate handling of amputated fingers, hands, and feet during the immediate transportation of the victim and body part to the hospital.

PART 1926—SAFETY AND HEALTH REGULATIONS FOR CONSTRUCTION

Subpart C—General Safety and Health Provisions

■ 17. The authority citation for subpart C continues to read as follows:

Authority: 40 U.S.C. 3701 *et seq.;* 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 6–96 (62 FR 111), 5–2007 (72 FR 31160), or 1–2012 (77 FR 3912) as applicable; and 29 CFR part 1911.

■ 18. In § 1926.20, revise paragraph (c) to read as follows:

§ 1926.20 General safety and health provisions.

* * * * *

(c) The standards contained in this part shall apply with respect to employments performed in a workplace in a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, Wake Island, Outer Continental Shelf lands defined in the Outer Continental Shelf Lands Act, and Johnston Island.

* * * * *

Subpart D—Occupational Health and Environmental Controls

■ 19. The authority citation for subpart D continues to read as follows:

Authority: 40 U.S.C. 3704; 29 U.S.C. 653, 655, and 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31159), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912); 29 CFR part 1911; and 5 U.S.C. 553, as applicable.

Section 1926.61 also issued under 49 U.S.C. 5101 *et seq.*

Section 1926.62 also issued under 42 U.S.C. 4853.

Section 1926.65 also issued under 126 of Public Law 99–499, 100 Stat. 1613.

■ 20. In § 1926.62, revise paragraphs (d)(2)(iii) introductory text, (d)(2)(iv), (d)(3)(iii), and (d)(4)(ii) and revise section IV paragraph (F) of appendix B to read as follows:

§ 1926.62 Lead.

* * * * *

(d) * * *

(2) * * *

(iii) With respect to the tasks listed in this paragraph (d)(2)(iii) of this section, where lead is present, until the employer performs an employee exposure assessment as required in this paragraph (d), and documents that the employee performing any of the listed tasks is not exposed in excess of 500 μg/m^3, the employer shall treat the employee as if the employee were exposed to lead in excess of 500 μg/m^3 and shall implement employee protective measures as prescribed in paragraph (d)(2)(v) of this section. Where the employer does establish that the employee is exposed to levels of lead below 500 μg/m^3, the employer may provide the exposed employee with the appropriate respirator prescribed for such use at such lower exposures, in accordance with paragraph (f) of this section. The tasks covered by this requirement are:

* * * * *

(iv) With respect to the tasks listed in this paragraph (d)(2)(iv), where lead is present, until the employer performs an employee exposure assessment as required in this paragraph (d) and documents that the employee performing any of the listed tasks is not exposed to lead in excess of 2,500 μg/m^3 (50×PEL), the employer shall treat the employee as if the employee were exposed to lead in excess of 2,500 μg/m^3 and shall implement employee protective measures as prescribed in paragraph (d)(2)(v) of this section. Where the employer does establish that the employee is exposed to levels of lead below 2,500 μg/m^3, the employer may provide the exposed employee with the appropriate respirator prescribed for use at such lower exposures, in accordance with paragraph (f) of this section. Interim protection as described in this paragraph is required where lead containing coatings or paint are present on structures when performing:

* * * * *

(3) * * *

(iii) Where the employer has previously monitored for lead exposures, and the data were obtained within the past 12 months during work operations conducted under workplace conditions closely resembling the processes, type of material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraphs (d)(3)(i) and (d)(6) of this section if the sampling and analytical methods meet the accuracy and confidence levels of paragraph (d)(9) of this section.

* * * * *

(4) * * *

(ii) Where the employer has previously monitored for lead exposure, and the data were obtained within the past 12 months during work operations conducted under workplace conditions closely resembling the processes, type of material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (d)(4)(i) of this section if the sampling and analytical methods meet the accuracy and confidence levels of paragraph (d)(9) of this section.

* * * * *

Appendix B to § 1926.62—Employee Standard Summary

* * * * *

IV. Respiratory Protection—Paragraph (F)

Your employer is required to provide and assure your use of respirators when your exposure to lead is not controlled below the PEL by other means. The employer must pay the cost of the respirator. Whenever you request one, your employer is also required to provide you a respirator even if your air exposure level is not above the PEL. You might desire a respirator when, for example, you have received medical advice that your lead absorption should be decreased. Or, you may intend to have children in the near future, and want to reduce the level of lead in your body to minimize adverse reproductive effects. While respirators are the least satisfactory means of controlling your exposure, they are capable of providing significant protection if properly chosen, fitted, worn, cleaned, maintained, and replaced when they stop providing adequate protection.

Your employer is required to select your respirator according to the requirements of 29 CFR 1926.62(f)(3), including the requirements referenced in 29 CFR 1910.134(d)(3)(i)(A) of this chapter. Any respirator chosen must be approved by NIOSH under the provisions of 42 CFR part 84. These respirator selection references will enable your employer to choose a type of respirator that will give you a proper amount of protection based on your airborne lead exposure. Your employer may select a type of respirator that provides greater protection than that required by the standard; that is, one recommended for a higher concentration of lead than is present in your workplace. For example, a powered air-purifying respirator (PAPR) is much more protective than a typical negative pressure respirator, and may also be more comfortable to wear. A PAPR has a filter, cartridge, or canister to clean the air, and a power source that continuously blows filtered air into your breathing zone. Your employer might make a PAPR available to you to ease the burden of having to wear a respirator for long periods of time. The standard provides that you can obtain a PAPR upon request.

Your employer must also start a Respiratory Protection Program. This

program must include written procedures for the proper selection, use, cleaning, storage, and maintenance of respirators.

Your employer must ensure that your respirator facepiece fits properly. Proper fit of a respirator facepiece is critical to your protection from airborne lead. Obtaining a proper fit on each employee may require your employer to make available several different types of respirator masks. To ensure that your respirator fits properly and that facepiece leakage is minimal, your employer must give you either a qualitative or quantitative fit test as specified in appendix A of the Respiratory Protection standard located at 29 CFR 1910.134.

You must also receive from your employer proper training in the use of respirators. Your employer is required to teach you how to wear a respirator, to know why it is needed, and to understand its limitations.

The standard provides that if your respirator uses filter elements, you must be given an opportunity to change the filter elements whenever an increase in breathing resistance is detected. You also must be permitted to periodically leave your work area to wash your face and respirator facepiece whenever necessary to prevent skin irritation. If you ever have difficulty in breathing during a fit test or while using a respirator, your employer must make a medical examination available to you to determine whether you can safely wear a respirator. The result of this examination may be to give you a positive pressure respirator (which reduces breathing resistance) or to provide alternative means of protection.

* * * * *

■ 21. In § 1926.65, revise paragraphs (a)(2)(i), (g)(2), (l)(3)(vi), (p)(8)(iv)(E), and (q)(3)(iii) and in appendix A revise paragraph 5.1 in section B to read as follows:

§ 1926.65 Hazardous waste operations and emergency response.

(a) * * *

(2) * * *

(i) All requirements of 29 CFR parts 1910 and 1926 apply pursuant to their terms to hazardous waste and emergency response operations whether covered by this section or not. If there is a conflict or overlap, the provision more protective of employee safety and health shall apply without regard to 29 CFR 1926.20(e).

* * * * *

(g) * * *

(2) *Engineering controls, work practices, and PPE for substances not regulated either in § 1926.55, elsewhere in subpart D, or in other pertinent sections of this Part.* An appropriate combination of engineering controls, work practices, and personal protective equipment shall be used to reduce and maintain employee exposure to or below published exposure levels for hazardous substances and health hazards not regulated either in § 1926.55, elsewhere in subpart D, or in other pertinent sections of this part. The employer may use the published literature and Safety Data Sheets (SDS) as a guide in making the employer's determination as to what level of protection the employer believes is appropriate for hazardous substances and health hazards for which there is no permissible exposure limit or published exposure limit.

* * * * *

(l) * * *

(3) * * *

(vi) An employee alarm system shall be installed to notify employees of an emergency situation; to stop work activities if necessary; to lower background noise in order to speed communication; and to begin emergency procedures.

* * * * *

(p) * * *

(8) * * *

(iv) * * *

(E) An employee alarm system shall be installed to notify employees of an emergency situation; to stop work activities if necessary; to lower background noise in order to speed communication; and to begin emergency procedures.

* * * * *

(q) * * *

(3) * * *

(iii) Based on the hazardous substances and/or conditions present, the individual in charge of the ICS shall implement appropriate emergency operations, and assure that the personal protective equipment worn is appropriate for the hazards to be encountered.

* * * * *

Appendix A to § 1926.65—Personal Protective Equipment Test Methods

* * * * *

B. Totally-Encapsulating Chemical Protective Suit Qualitative Leak Test

* * * * *

5.1 Concentrated aqueous ammonium hydroxide, NH_4 OH, is a corrosive volatile liquid requiring eye, skin, and respiratory protection. The person conducting the test shall review the Safety Data Sheet (SDS) for aqueous ammonia.

* * * * *

Subpart K—Electrical

■ 22. The authority citation for subpart K is revised to read as follows:

Authority: 29 U.S.C. 653, 655, 657; 40 U.S.C. 333; Secretary of Labor's Order No. 9–83 (48 FR 35736), 1–90 (55 FR 9033) or 1–2012 (77 FR 3912), as applicable; 29 CFR part 1911.

* * * * *

■ 23. In § 1926.405, revise paragraph (g)(1)(iii)(C) to read as follows:

§ 1926.405 Wiring methods, components, and equipment for general use.

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(C) Where run through doorways, windows, or similar openings, except as permitted in paragraph (a)(2)(ii)(I) of this section;

* * * * *

Subpart L—Scaffolds

■ 24. The authority citation for subpart L continues to read as follows:

Authority: 40 U.S.C. 333; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order Nos. 1–90 (55 FR 9033), 5–2007 (72 FR 31159), or 1–2012 (77 FR 3912); and 29 CFR part 1911.

* * * * *

■ 25. In § 1926.452, revise paragraphs (a)(3) and (w)(6)(ii) to read as follows:

§ 1926.452 Additional requirements applicable to specific types of scaffolds.

* * * * *

(a) * * *

(3) Diagonal bracing in both directions shall be installed across the entire inside face of double-pole scaffolds used to support loads equivalent to a uniformly distributed load of 50 pounds (22.7 kg) or more per square foot (929 square cm).

* * * * *

(w) * * *

(6) * * *

(ii) The height to base width ratio of the scaffold during movement is two to one or less, unless the scaffold is designed and constructed to meet or exceed nationally recognized stability test requirements such as those listed in paragraph 2.(w) of appendix A to this subpart;

* * * * *

■ 26. In appendix E to subpart L of part 1926 subpart L:

■ a. Remove the graphic ''Maximum Vertical Tie Spacing Wider Than 3′-0″ Bases'' and add in its place the graphic ''Maximum Vertical Guy, Tie or Brace Spacing Wider Than 3′-0″ Bases''; and

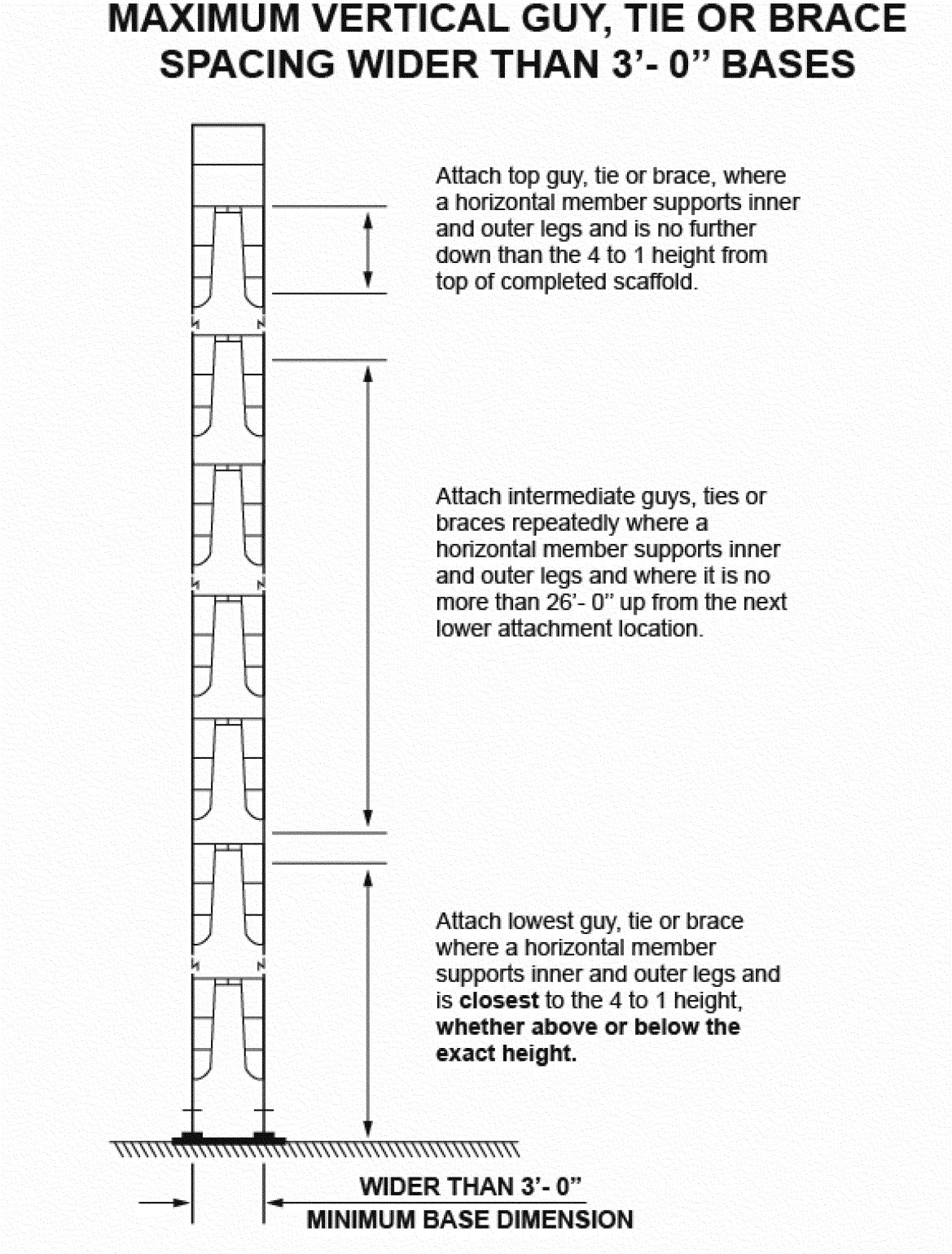
■ b. Remove the graphic ''Maximum Vertical Tie Spacing 3′-0″and Narrower Bases'' and add in its place the ''Maximum Vertical Guy, Tie or Brace Spacing 3′-0″ And Narrower Bases''.

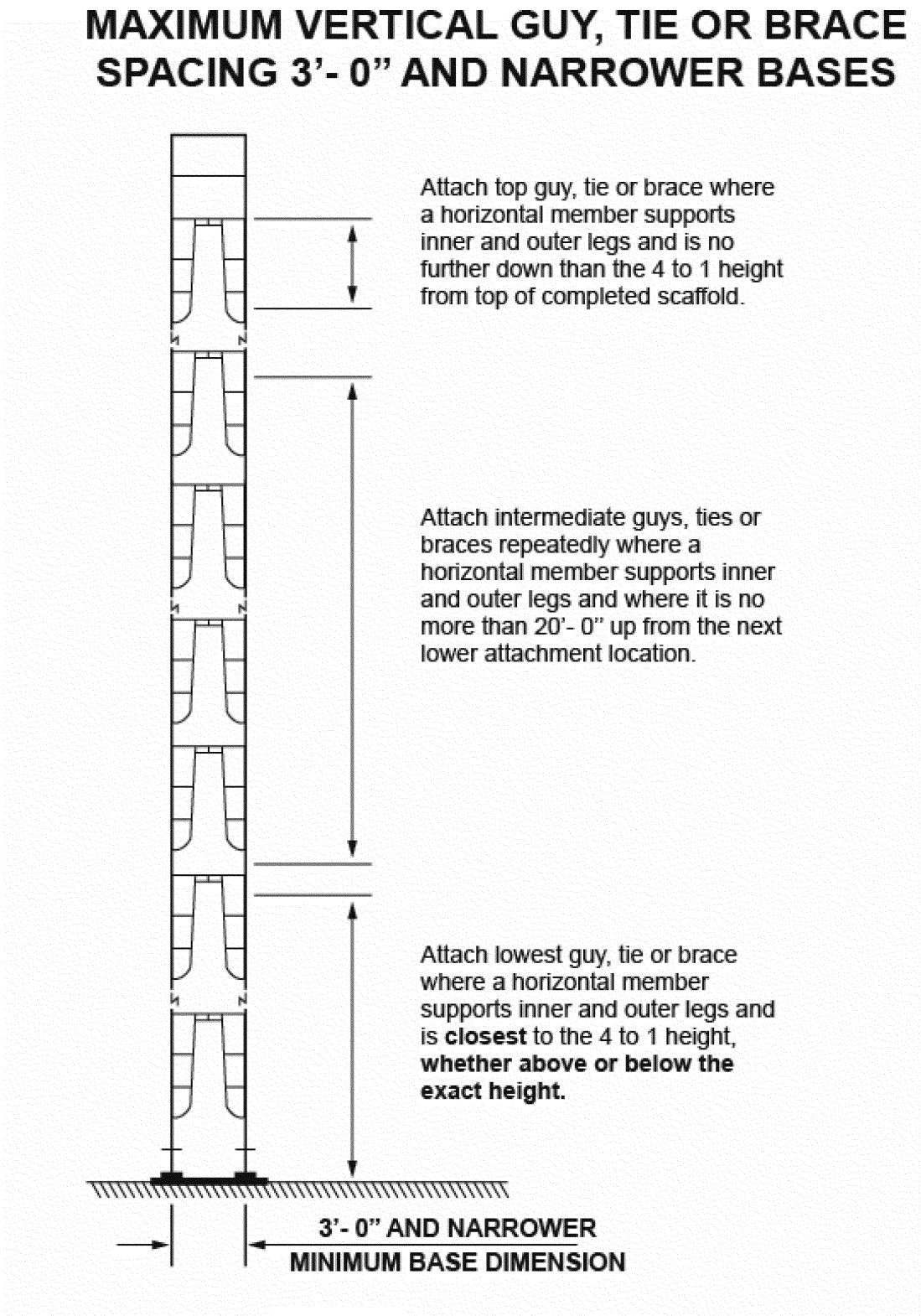
The additions read as follows:

BILLING CODE 4510–26–P

(Non-Mandatory) Appendix E to Subpart L of Part 1926—Drawings and Illustrations

* * * * *





View or download PDF

* * * * *

Subpart M—Fall Protection

■ 27. The authority citation for subpart M continues to read as follows:

Authority: 40 U.S.C. 3701 *et seq.;* 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2007 (72 FR 31159), or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

■ 28. Revise appendix A to subpart M of part 1926 to read as follows:

Appendix A to Subpart M of Part 1926—Determining Roof Widths

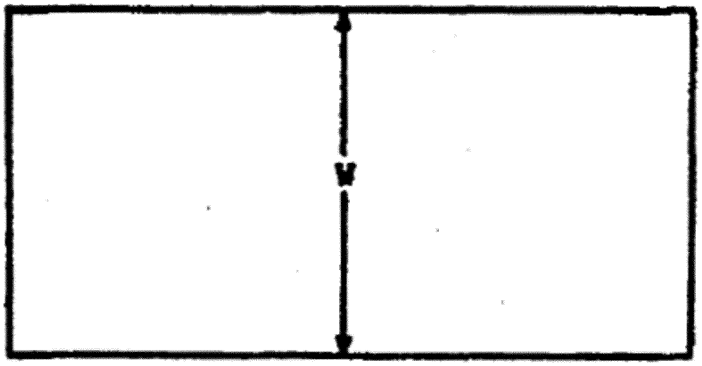
Non-Mandatory Guidelines for Complying With § 1926.501(b)(10)

(1) This appendix serves as a guideline to assist employers complying with the requirements of § 1926.501(b)(10). Section 1926.501(b)(10) allows the use of a safety monitoring system alone as a means of providing fall protection during the performance of roofing operations on low-sloped roofs 50 feet (15.25 m) or less in width. Each example in the appendix shows a roof plan or plans and indicates where each roof or roof area is to be measured to determine its width. Section views or elevation views are shown where appropriate. Some examples show ''correct'' and ''incorrect'' subdivisions of irregularly shaped roofs divided into smaller, regularly shaped areas. In all examples, the dimension selected to be the width of an area is the lesser of the two primary dimensions of the area, as viewed from above. Example A shows that on a simple rectangular roof, width is the lesser of the two primary overall dimensions. This is also the case with roofs which are sloped toward or away from the roof center, as shown in Example B.

(2) Many roofs are not simple rectangles. Such roofs may be broken down into subareas as shown in Example C. The process of dividing a roof area can produce many different configurations. Example C gives the general rule of using dividing lines of minimum length to minimize the size and number of the areas which are potentially less than 50 feet (15.25 m) wide. The intent is to minimize the number of roof areas where safety monitoring systems alone are sufficient protection.

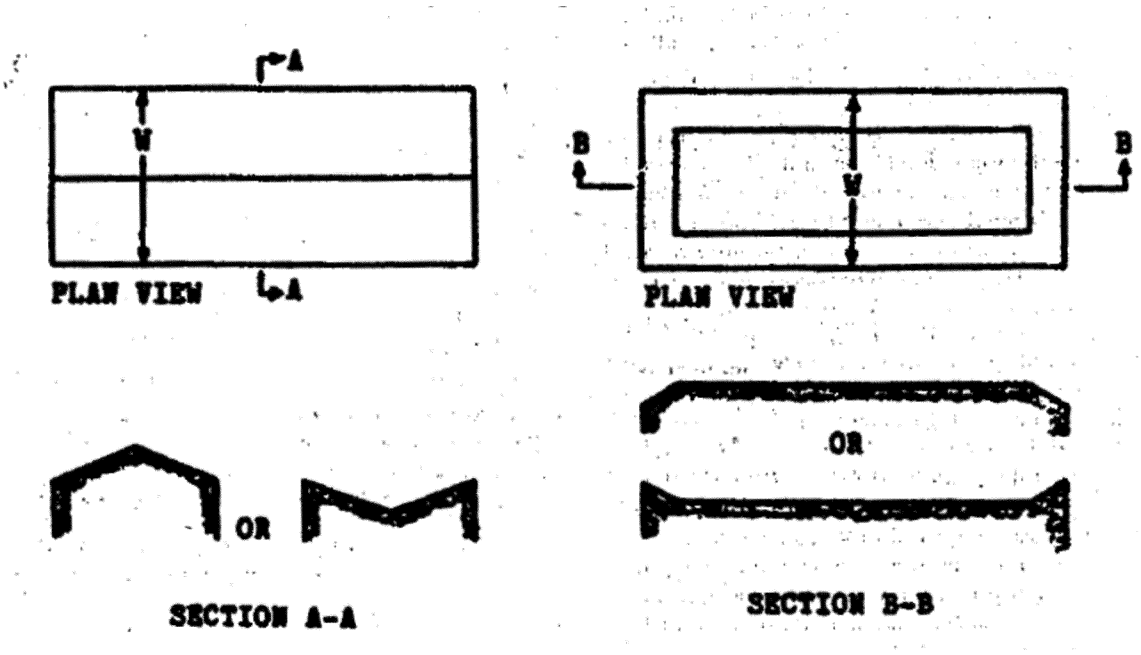
(3) Roofs which are comprised of several separate, non-contiguous roof areas, as in Example D, may be considered as a series of individual roofs. Some roofs have penthouses, additional floors, courtyard openings, or similar architectural features; Example E shows how the rule for dividing roofs into subareas is applied to such configurations. Irregular, non-rectangular roofs must be considered on an individual basis, as shown in Example F.

EXAMPLE A: RECTANGULAR SHAPED ROOFS



PLAN VIEW

EXAMPLE B: SLOPED RECTANGULAR SHAPED ROOFS



PLAN VIEW

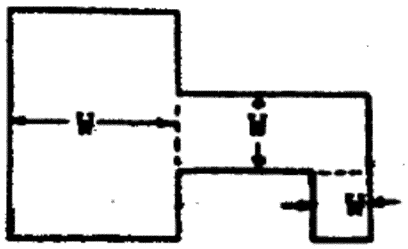
PLAN VIEW

SECTION A-A

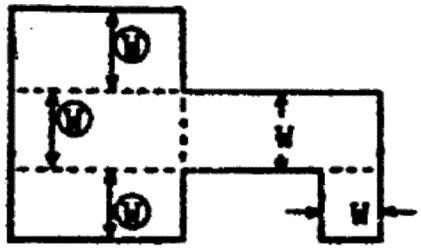
SECTION B-B

EXAMPLE C: IRREGULARLY SHAPED ROOFS WITH RECTANGULAR SHAPED SECTIONS

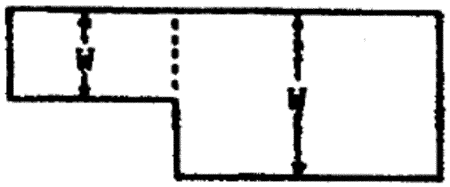
Such roofs are to be divided into sub-areas by using dividing lines of minimum length to minimize the size and number of the areas which are potentially less than or equal to 50 feet (15.25 meters) in width, in order to limit the size of roof areas where the safety monitoring system alone can be used [1926.501(b)(10)]. Dotted lines are used in the examples to show the location of dividing lines. W denotes correct measurements and Ⓦ denotes incorrect measurements of width.



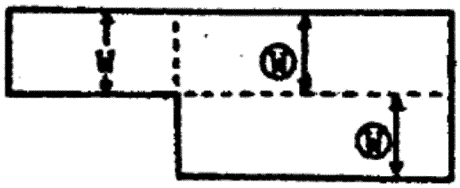
Correct



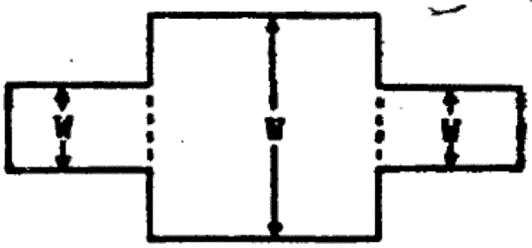
Incorrect



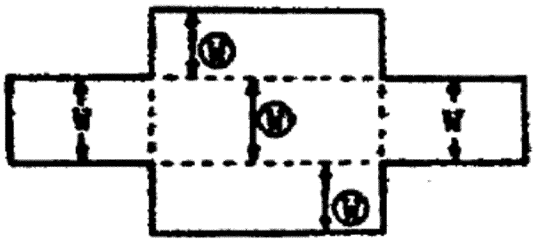
Correct



Incorrect



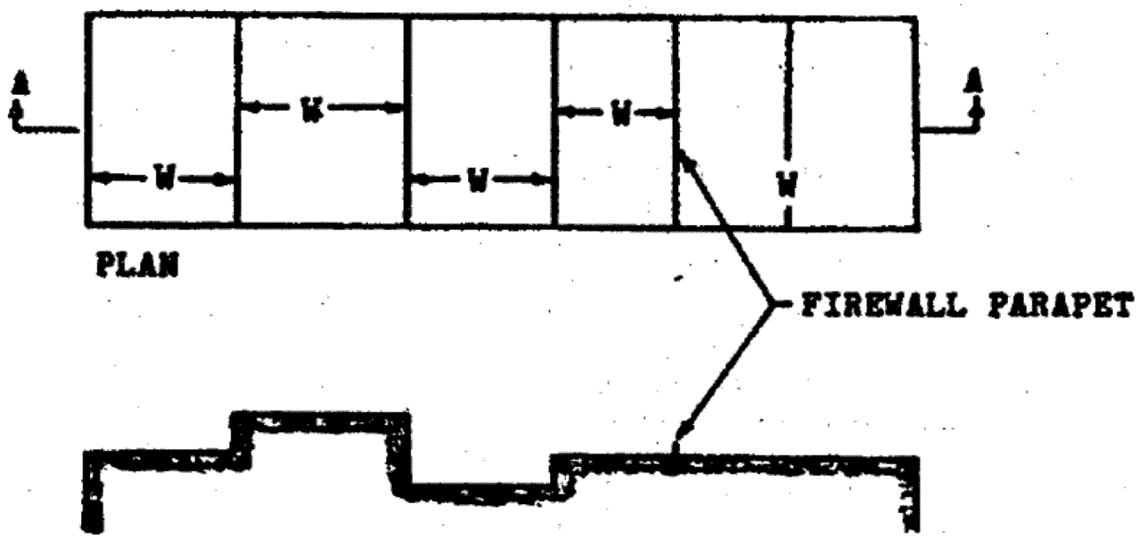
Correct



Incorrect

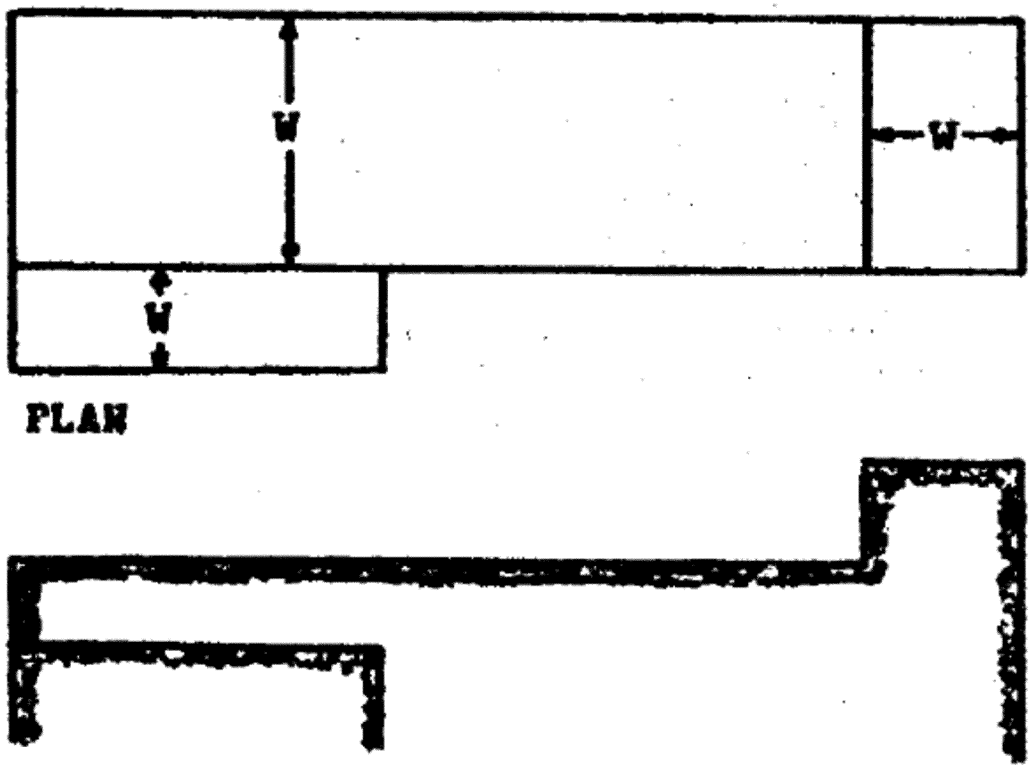
EXAMPLE D: SEPARATE, NON-CONTIGUOUS ROOF AREAS

1.



SECTION A–A

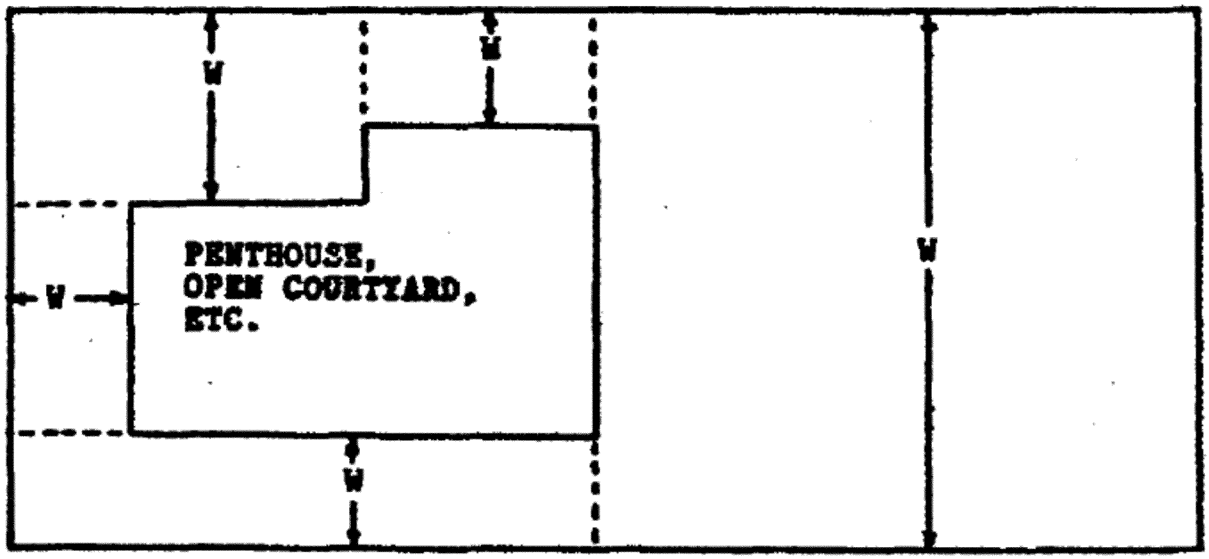
2.



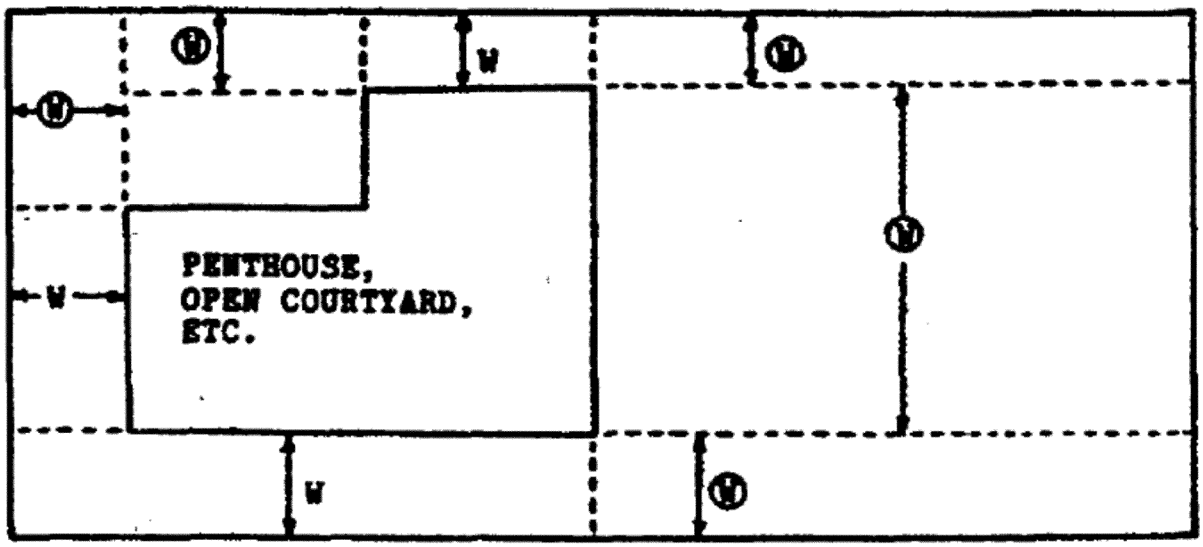
ELEVATION

EXAMPLE E: ROOFS WITH PENTHOUSES, OPEN COURTYARDS, ADDITIONAL FLOORS, ETC.

Such roofs are to be divided into sub-areas by using dividing lines of minimum length to minimize the size and number of the areas which are potentially less than or equal to 50 feet (15.25 meters) in width, in order to limit the size of roof areas where the safety monitoring system alone can be used [1926.501(b)(10)]. Dotted lines are used in the examples to show the location of dividing lines. W denotes correct and Ⓦ denotes incorrect measurements of width.

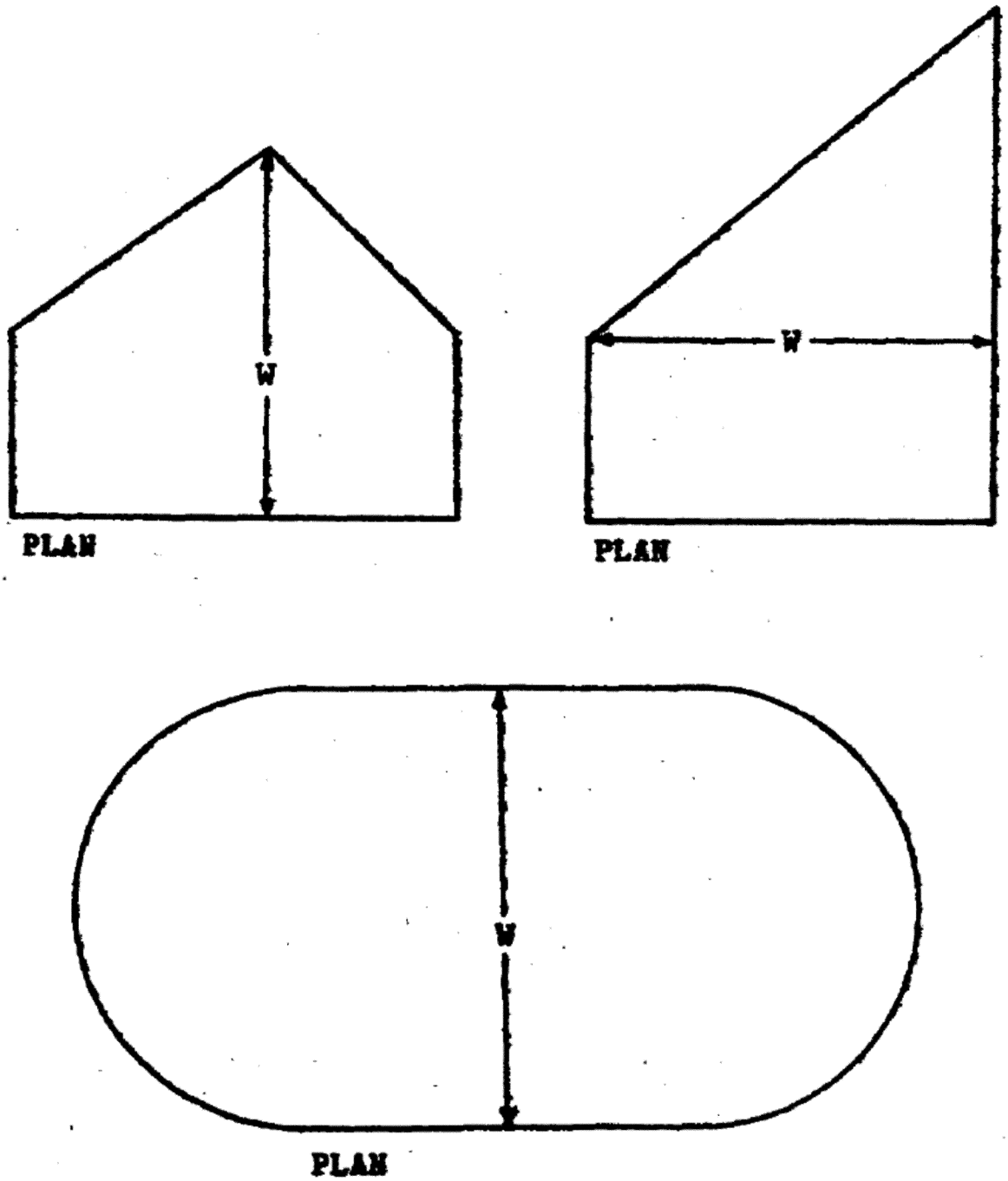


Correct



Incorrect

EXAMPLE F: IRREGULAR, NON-RECTANGULAR SHAPED ROOFS



BILLING CODE 4510–26–C

Subpart N—Helicopters, Hoists, Elevators, and Conveyors

■ 29. The authority citation for subpart N is revised to read as follows:

Authority: 40 U.S.C. 3701; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (49 FR 35736), 5–2007 (72 FR 31159), or 1–2012 (77 FR 3912), as applicable; and 29 CFR 1911.

§ 1926.552 [Amended]

■ 30. In § 1926.552, in paragraph (c)(17)(iv), redesignate paragraphs (*a*) through (*e*) as paragraphs (A) through (E).

Subpart P—Excavations

■ 31. The authority citation for subpart P is revised to read as follows:

Authority: 40 U.S.C. 333; 29 U.S.C. 653, 655, and 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

■ 32. Revise appendix A to subpart P of part 1926 to read as follows:

Appendix A to Subpart P of Part 1926—Soil Classification

(a) *Scope and application*—(1) *Scope.* This appendix describes a method of classifying soil and rock deposits based on site and environmental conditions, and on the

structure and composition of the earth deposits. The appendix contains definitions, sets forth requirements, and describes acceptable visual and manual tests for use in classifying soils.

(2) *Application.* This appendix applies when a sloping or benching system is designed in accordance with the requirements set forth in § 1926.652(b)(2) as a method of protection for employees from cave-ins. This appendix also applies when timber shoring for excavations is designed as a method of protection from cave-ins in accordance with appendix C to subpart P of part 1926, and when aluminum hydraulic shoring is designed in accordance with appendix D. This appendix also applies if other protective systems are designed and selected for use from data prepared in accordance with the requirements set forth in § 1926.652(c), and the use of the data is predicated on the use of the soil classification system set forth in this appendix.

(b) *Definitions.* The definitions and examples given below are based on, in whole or in part, the following: American Society for Testing Materials (ASTM) Standards D653–85 and D2488; The Unified Soils Classification System, the U.S. Department of Agriculture (USDA) Textural Classification Scheme; and The National Bureau of Standards Report BSS–121.

Cemented soil means a soil in which the particles are held together by a chemical agent, such as calcium carbonate, such that a hand-size sample cannot be crushed into powder or individual soil particles by finger pressure.

Cohesive soil means clay (fine grained soil), or soil with a high clay content, which has cohesive strength. Cohesive soil does not crumble, can be excavated with vertical sideslopes, and is plastic when moist. Cohesive soil is hard to break up when dry, and exhibits significant cohesion when submerged. Cohesive soils include clayey silt, sandy clay, silty clay, clay and organic clay.

Dry soil means soil that does not exhibit visible signs of moisture content.

Fissured means a soil material that has a tendency to break along definite planes of fracture with little resistance, or a material that exhibits open cracks, such as tension cracks, in an exposed surface.

Granular soil means gravel, sand, or silt, (coarse grained soil) with little or no clay content. Granular soil has no cohesive strength. Some moist granular soils exhibit apparent cohesion. Granular soil cannot be molded when moist and crumbles easily when dry.

Layered system means two or more distinctly different soil or rock types arranged in layers. Micaceous seams or weakened planes in rock or shale are considered layered.

Moist soil means a condition in which a soil looks and feels damp. Moist cohesive soil can easily be shaped into a ball and rolled into small diameter threads before crumbling. Moist granular soil that contains some cohesive material will exhibit signs of cohesion between particles.

Plastic means a property of a soil which allows the soil to be deformed or molded without cracking, or appreciable volume change.

Saturated soil means a soil in which the voids are filled with water. Saturation does not require flow. Saturation, or near saturation, is necessary for the proper use of instruments such as a pocket penetrometer or sheer vane.

Soil classification system means, for the purpose of this subpart, a method of categorizing soil and rock deposits in a hierarchy of Stable Rock, Type A, Type B, and Type C, in decreasing order of stability. The categories are determined based on an analysis of the properties and performance characteristics of the deposits and the environmental conditions of exposure.

Stable rock means natural solid mineral matter that can be excavated with vertical sides and remain intact while exposed.

Submerged soil means soil which is underwater or is free seeping.

Type A means cohesive soils with an unconfined compressive strength of 1.5 ton per square foot (tsf) (144 kPa) or greater. Examples of cohesive soils are: clay, silty clay, sandy clay, clay loam and, in some cases, silty clay loam and sandy clay loam. Cemented soils such as caliche and hardpan are also considered Type A. However, no soil is Type A if:

(i) The soil is fissured; or

(ii) The soil is subject to vibration from heavy traffic, pile driving, or similar effects; or

(iii) The soil has been previously disturbed; or

(iv) The soil is part of a sloped, layered system where the layers dip into the excavation on a slope of four horizontal to one vertical (4H:1V) or greater; or

(v) The material is subject to other factors that would require it to be classified as a less stable material.

Type B means:

(i) Cohesive soil with an unconfined compressive strength greater than 0.5 tsf (48 kPa) but less than 1.5 tsf (144 kPa); or

(ii) Granular cohesionless soils including: angular gravel (similar to crushed rock), silt, silt loam, sandy loam and, in some cases, silty clay loam and sandy clay loam.

(iii) Previously disturbed soils except those which would otherwise be classified as Type C soil.

(iv) Soil that meets the unconfined compressive strength or cementation requirements for Type A, but is fissured or subject to vibration; or

(v) Dry rock that is not stable; or

(vi) Material that is part of a sloped, layered system where the layers dip into the excavation on a slope less steep than four horizontal to one vertical (4H:1V), but only if the material would otherwise be classified as Type B.

Type C means:

(i) Cohesive soil with an unconfined compressive strength of 0.5 tsf (48 kPa) or less; or

(ii) Granular soils including gravel, sand, and loamy sand; or

(iii) Submerged soil or soil from which water is freely seeping; or

(iv) Submerged rock that is not stable; or

(v) Material in a sloped, layered system where the layers dip into the excavation on a slope of four horizontal to one vertical (4H:1V) or steeper.

Unconfined compressive strength means the load per unit area at which a soil will fail in compression. It can be determined by laboratory testing, or estimated in the field using a pocket penetrometer, by thumb penetration tests, and other methods.

Wet soil means soil that contains significantly more moisture than moist soil, but in such a range of values that cohesive material will slump or begin to flow when vibrated. Granular material that would exhibit cohesive properties when moist will lose those cohesive properties when wet.

(c) *Requirements*—(1) *Classification of soil and rock deposits.* Each soil and rock deposit shall be classified by a competent person as Stable Rock, Type A, Type B, or Type C in accordance with the definitions set forth in paragraph (b) of this appendix.

(2) *Basis of classification.* The classification of the deposits shall be made based on the results of at least one visual and at least one manual analysis. Such analyses shall be conducted by a competent person using tests described in paragraph (d) below, or in other recognized methods of soil classification and testing such as those adopted by the America Society for Testing Materials, or the U.S. Department of Agriculture textural classification system.

(3) *Visual and manual analyses.* The visual and manual analyses, such as those noted as being acceptable in paragraph (d) of this appendix, shall be designed and conducted to provide sufficient quantitative and qualitative information as may be necessary to identify properly the properties, factors, and conditions affecting the classification of the deposits.

(4) *Layered systems.* In a layered system, the system shall be classified in accordance with its weakest layer. However, each layer may be classified individually where a more stable layer lies under a less stable layer.

(5) *Reclassification.* If, after classifying a deposit, the properties, factors, or conditions affecting its classification change in any way, the changes shall be evaluated by a competent person. The deposit shall be reclassified as necessary to reflect the changed circumstances.

(d) *Acceptable visual and manual tests*—(1) *Visual tests.* Visual analysis is conducted to determine qualitative information regarding the excavation site in general, the soil adjacent to the excavation, the soil forming the sides of the open excavation, and the soil taken as samples from excavated material.

(i) Observe samples of soil that are excavated and soil in the sides of the excavation. Estimate the range of particle sizes and the relative amounts of the particle sizes. Soil that is primarily composed of fine-grained material is cohesive material. Soil composed primarily of coarse-grained sand or gravel is granular material.

(ii) Observe soil as it is excavated. Soil that remains in clumps when excavated is cohesive. Soil that breaks up easily and does not stay in clumps is granular.

(iii) Observe the side of the opened excavation and the surface area adjacent to the excavation. Crack-like openings such as

tension cracks could indicate fissured material. If chunks of soil spall off a vertical side, the soil could be fissured. Small spalls are evidence of moving ground and are indications of potentially hazardous situations.

(iv) Observe the area adjacent to the excavation and the excavation itself for evidence of existing utility and other underground structures, and to identify previously disturbed soil.

(v) Observe the opened side of the excavation to identify layered systems. Examine layered systems to identify if the layers slope toward the excavation. Estimate the degree of slope of the layers.

(vi) Observe the area adjacent to the excavation and the sides of the opened excavation for evidence of surface water, water seeping from the sides of the excavation, or the location of the level of the water table.

(vii) Observe the area adjacent to the excavation and the area within the excavation for sources of vibration that may affect the stability of the excavation face.

(2) *Manual tests.* Manual analysis of soil samples is conducted to determine quantitative as well as qualitative properties of soil and to provide more information in order to classify soil properly.

(i) *Plasticity.* Mold a moist or wet sample of soil into a ball and attempt to roll it into threads as thin as ⅛-inch in diameter. Cohesive material can be successfully rolled into threads without crumbling. For example, if at least a two inch (50 mm) length of ⅛-inch thread can be held on one end without tearing, the soil is cohesive.

(ii) *Dry strength.* If the soil is dry and crumbles on its own or with moderate pressure into individual grains or fine powder, it is granular (any combination of gravel, sand, or silt). If the soil is dry and falls into clumps which break up into smaller clumps, but the smaller clumps can only be broken up with difficulty, it may be clay in any combination with gravel, sand or silt. If the dry soil breaks into clumps which do not break up into small clumps and which can only be broken with difficulty, and there is no visual indication the soil is fissured, the soil may be considered unfissured.

(iii) *Thumb penetration.* The thumb penetration test can be used to estimate the unconfined compressive strength of cohesive soils. (This test is based on the thumb penetration test described in American Society for Testing and Materials (ASTM) Standard designation D2488—''Standard Recommended Practice for Description of Soils (Visual—Manual Procedure).'') Type A soils with an unconfined compressive strength of 1.5 tsf can be readily indented by the thumb; however, they can be penetrated by the thumb only with very great effort. Type C soils with an unconfined compressive strength of 0.5 tsf can be easily penetrated several inches by the thumb, and can be molded by light finger pressure. This test should be conducted on an undisturbed soil sample, such as a large clump of spoil, as soon as practicable after excavation to keep to a minimum the effects of exposure to drying influences. If the excavation is later exposed to wetting influences (rain, flooding), the classification of the soil must be changed accordingly.

(iv) *Other strength tests.* Estimates of unconfined compressive strength of soils can also be obtained by use of a pocket penetrometer or by using a hand-operated shearvane.

(v) *Drying test.* The basic purpose of the drying test is to differentiate between cohesive material with fissures, unfissured cohesive material, and granular material. The procedure for the drying test involves drying a sample of soil that is approximately one inch thick (2.54 cm) and six inches (15.24 cm) in diameter until it is thoroughly dry:

(A) If the sample develops cracks as it dries, significant fissures are indicated.

(B) Samples that dry without cracking are to be broken by hand. If considerable force is necessary to break a sample, the soil has significant cohesive material content. The soil can be classified as an unfissured cohesive material and the unconfined compressive strength should be determined.

(C) If a sample breaks easily by hand, it is either a fissured cohesive material or a granular material. To distinguish between the two, pulverize the dried clumps of the sample by hand or by stepping on them. If the clumps do not pulverize easily, the material is cohesive with fissures. If they pulverize easily into very small fragments, the material is granular

Subpart R—Steel Erection

■ 33. The authority citation for subpart R is revised to read as follows:

Authority: 40 U.S.C. 3701; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order Nos. 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31159), or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

■ 34. In § 1926.754, revise paragraph (c)(2) to read as follows;

§ 1926.754 Structural steel assembly.

* * * * *

(c) * * *

(2) *Installation of shear connectors on composite floors, roofs and bridge decks.* When shear connectors are used in construction of composite floors, roofs and bridge decks, employees shall lay out and install the shear connectors after the metal decking has been installed, using the metal decking as a working platform. Shear connectors shall not be installed from within a controlled decking zone (CDZ), as specified in § 1926.760(c)(7).

* * * * *

■ 35. In § 1926.757, revise the footnotes to Tables A and B to read as follows:

§ 1926.757 Open web steel joists

* * * * *

TABLE A—ERECTION BRIDGING FOR SHORT SPAN JOISTS

Joist	Span
* * * * *	

NM = diagonal bolted bridging not mandatory.

* * * * *

TABLE B—ERECTION BRIDGING FOR LONG SPAN JOISTS

Joist	Span
* * * * *	

NM = diagonal bolted bridging not mandatory.

* * * * *

■ 36. In § 1926.761, revise paragraph (b) to read as follows:

§ 1926.761 Training.

* * * * *

(b) *Fall hazard training.* The employer shall train each employee exposed to a fall hazard in accordance with the requirements of this section. The employer shall institute a training program and ensure employee participation in the program. The program shall include training and instruction in the following areas:

(1) The recognition and identification of fall hazards in the work area;

(2) The use and operation of guardrail systems (including perimeter safety cable systems), personal fall arrest systems, positioning device systems, fall restraint systems, safety net systems, and other protection to be used;

(3) The correct procedures for erecting, maintaining, disassembling, and inspecting the fall protection systems to be used;

(4) The procedures to be followed to prevent falls to lower levels and through or into holes and openings in walking/working surfaces and walls; and

(5) The fall protection requirements of this subpart.

* * * * *

Subpart V—Electric Power Transmission and Distribution

■ 37. The authority citation for subpart V continues to read as follows:

Authority: 40 U.S.C. 3701 *et seq.;* 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 1–2012 (77 FR 3912); and 29 CFR part 1911.

■ 38. In § 1926.968, in the definition of ''Hazardous atmosphere'', revise the note following paragraph (5) to read as follows:

§ 1926.968 Definitions.

* * * * *

Hazardous atmosphere. * * *

(5) * * *

Note to the Definition of ''Hazardous Atmosphere'' (5): For air contaminants for which the Occupational Safety and Health Administration has not determined a dose or permissible exposure limit, other sources of information, such as Safety Data Sheets (SDS) that comply with the Hazard Communication Standard, § 1910.1200, published information, and internal documents can provide guidance in establishing acceptable atmospheric conditions.

* * * * *

Subpart Z—Toxic and Hazardous Substances

■ 39. The authority citation for subpart Z continues to read as follows:

Authority: 40 U.S.C. 3704; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912) as applicable; 29 CFR part 1911; and 5 U.S.C. 553, as applicable.

■ 40. In § 1926.1101, revise paragraphs (e)(4) and (f)(3)(iii), the paragraph (g)(7) subject heading, paragraphs (g)(8)(v) introductory text, (n)(2)(iii), (n)(3)(i) and (iii), and (p)(1), and in appendix K, in section 3.1, revise paragraph (e) to read as follows:

§ 1926.1101 Asbestos.

* * * * *

(e) * * *

(4) *Respirators.* All persons entering a regulated area where employees are required pursuant to paragraph (h)(1) of this section to wear respirators shall be supplied with a respirator selected in accordance with paragraph (h)(3) of this section.

* * *

(f) * * *

(3) * * *

(iii) Exception: When all employees required to be monitored daily are equipped with supplied-air respirators operated in the pressure demand mode, or other positive pressure mode, the employer may dispense with the daily monitoring required by this paragraph. However, employees performing Class I work using a control method which is not listed in paragraph (g)(4)(i), (ii), or (iii) of this section or using a modification of a listed control method, shall continue to be monitored daily even if they are equipped with supplied-air respirators.

* * * * *

(g) * * *

(7) *Work Practices and Engineering Controls for Class II work.* * * *

* * * * *

(8) * * *

(v) When performing any other Class II removal of asbestos containing material for which specific controls have not been listed in paragraph (g)(8)(i) through (iv) of this section, the employer shall ensure that the following work practices are complied with.

* * * * *

(n) * * *

(2) * * *

(iii) The employer shall maintain this record for at least thirty (30) years, in accordance with § 1910.1020 of this chapter

(3) * * *

(i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance by paragraph (m) of this section, in accordance with § 1910.1020 of this chapter.

* * * * *

(iii) The employer shall ensure that this record is maintained for the duration of employment plus thirty (30) years, in accordance with § 1910.1020 of this chapter.

* * * * *

(p) * * *

(1) Appendices A, D, and E to this section are incorporated as part of this section and the contents of these appendices are mandatory.

* * * * *

Appendix K to § 1926.1101—Polarized Light Microscopy of Asbestos (Non-Mandatory)

* * * * *

3.1. Safety

* * * * *

(e) Some of the solvents used, such as THF (tetrahydrofuran), are toxic and should only be handled in an appropriate fume hood and according to instructions given in the Safety Data Sheet (SDS).

* * * * *

■ 41. In § 1926.1127, revise paragraphs (d)(1)(i), (n)(1)(iii), and (n)(3)(iii) and remove paragraph (n)(5).

The revisions read as follows:

§ 1926.1127 Cadmium.

* * * * *

(d) * * *

(1) * * *

(i) Prior to the performance of any construction work where employees may be potentially exposed to cadmium, the employer shall establish the applicability of this standard by determining whether cadmium is present in the workplace and whether there is the possibility that employee exposures will be at or above the action level. The employer shall designate a competent person who shall make this determination. Investigation and material testing techniques shall be used, as appropriate, in the determination. Investigation shall include a review of relevant plans, past reports, Safety Data Sheets (SDS), and other available records, and consultations with the property owner and discussions with appropriate individuals and agencies.

* * * * *

(n) * * *

(1) * * *

(iii) The employer shall maintain this record for at least thirty (30) years, in accordance with § 1910.1020 of this chapter.

* * * * *

(3) * * *

(iii) The employer shall assure that this record is maintained for the duration of employment plus thirty (30) years, in accordance with § 1910.1020 of this chapter.

* * * * *

Subpart CC—Cranes and Derricks in Construction

■ 42. The authority citation for Part 1926 subpart CC continues to read as follows:

Authority: 40 U.S.C. 3701 *et seq.;* 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 5–2007 (72 FR 31159) or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

■ 43. In § 1926.1431, revise paragraph (a) to read as follows:

§ 1926.1431 Hoisting personnel.

* * * * *

(a) The use of equipment to hoist employees is prohibited except where the employer demonstrates that the erection, use, and dismantling of conventional means of reaching the work area, such as a personnel hoist, ladder, stairway, aerial lift, elevating work platform, or scaffold, would be more hazardous, or is not possible because of the project's structural design or worksite conditions. This paragraph does not apply to work covered by subpart R (Steel Erection) of this part and also does not apply to routine personnel access to an underground worksite via shaft as covered by § 1926.800 (Underground Construction) of this part.

* * * * *

[FR Doc. 2020–00207 Filed 2–14–20; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF THE TREASURY

Office of Investment Security

31 CFR Parts 800 and 802

RIN 1505–AC63, 1505–AC64

Provisions Pertaining to Certain Investments in the United States by Foreign Persons and Provisions Pertaining to Certain Transactions by Foreign Persons Involving Real Estate in the United States; Correction

AGENCY: Office of Investment Security, Department of the Treasury.

ACTION: Final rule; technical corrections.

SUMMARY: On January 17, 2020, the Department of the Treasury published two final rules implementing provisions of section 721 of the Defense Production Act of 1950, as amended by the Foreign Investment Risk Review Modernization Act of 2018. This final rule makes a limited number of technical corrections to those rules to provide clarity.

DATES: Effective February 13, 2020.

FOR FURTHER INFORMATION CONTACT: Laura Black, Director of Investment Security Policy and International Relations; Meena R. Sharma, Deputy Director of Investment Security Policy and International Relations; David Shogren, Senior Policy Advisor; or Alexander Sevald, Senior Policy Advisor, at U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220; telephone: (202) 622–3425; email: *CFIUS.FIRRMA@treasury.gov.*

SUPPLEMENTARY INFORMATION: This rule makes technical corrections to a limited number of provisions in 85 FR 3112 (January 17, 2020) and 85 FR 3158 (January 17, 2020). These changes are intended to improve the clarity of the rule.

■ In FR Doc. 2020–00188, appearing on page 3112 in the **Federal Register** on Friday, January 17, 2020, make the following corrections:

§ 800.219 [Corrected]

1. On page 3129, in the first column, in § 800.219, in paragraph (a)(3) introductory text, ''A foreign entity that meets each of the following conditions with respect to itself and each of its parents (if any):'' is corrected to read, ''An entity that meets each of the following conditions with respect to itself and each of its parents (if any):''.

2. On page 3129, in the first column, in § 800.219, paragraph (a)(3)(iv)(C) is corrected to read:

''(C) An entity that is organized under the laws of an excepted foreign state or in the United States and has its principal place of business in an excepted foreign state or in the United States; and''

3. On page 3129, in the first column, in § 800.219, paragraph (a)(3)(v)(D) is corrected to read:

''(D) An entity that is organized under the laws of an excepted foreign state or in the United States and has its principal place of business in an excepted foreign state or in the United States.''

§ 800.401 [Corrected]

4. On page 3140, in the third column, in § 800.401, correct paragraph (e)(4) by removing the word ''or'' following the semicolon and correct paragraph (e)(5) to read:

''(5) A covered control transaction involving an air carrier, as defined in 49 U.S.C. 40102(a)(2), that holds a certificate issued under 49 U.S.C. 41102; or''.

§ 800.502 [Corrected]

5. On page 3146, in the third column, in § 800.502, paragraph (c)(4)(i) is corrected to read:

''(i) Possesses any licenses, permits, or other authorizations other than those under the regulatory authorities listed in paragraph (c)(3)(x)(A) of this section that have been granted by an agency of the U.S. Government (if applicable, identification of the relevant licenses shall be provided); or''

6. On page 3148, in the third column, in § 800.502, in paragraph (o), the third sentence is corrected to read:

''(o) * * * The required description of the basis shall include discussion of all relevant information responsive to paragraphs (c)(5)(iii) through (v) of this section. * * *''

In FR Doc. 2020–00187, appearing on page 3158 in the **Federal Register** on Friday, January 17, 2020, make the following corrections:

§ 802.215 [Corrected]

7. On page 3169, in the first column, in § 802.215, correct paragraph (a)(3) introductory text to read:

''(3) An entity that meets each of the following conditions with respect to itself and each of its parents (if any):''

8. On page 3169, in the second column, in § 802.215, paragraph (a)(3)(iv)(C) is corrected to read:

''(C) An entity that is organized under the laws of an excepted real estate foreign state or in the United States and has its principal place of business in an excepted real estate foreign state or in the United States; and''

9. On page 3169, in the second column, in § 802.215, paragraph (a)(3)(v)(D) is corrected to read:

''(D) An entity that is organized under the laws of an excepted real estate foreign state or in the United States and has its principal place of business in an excepted real estate foreign state or in the United States.''

Dated: February 6, 2020.

Laura Black,

Director, Office of Investment Security Policy and International Relations.

[FR Doc. 2020–02713 Filed 2–13–20; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2019–0086]

RIN 1625–AA09

Drawbridge Operation Regulation; Hackensack River, Little Snake Hill, NJ

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is modifying the operating schedule that governs the Amtrak Portal Bridge across the Hackensack River, mile 5.0 at Little Snake Hill, New Jersey. The bridge owner, National Railroad Passenger Corporation (Amtrak), submitted a request to require a greater advance notice for bridge openings, to increase the time periods the bridge remains in the closed position, and to reduce bridge openings during the morning and evening commuter rush hours. It is expected that this change to the regulations will better serve the needs of the community while continuing to meet the reasonable needs of navigation.

DATES: This rule is effective March 19, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov.* Type USCG–2019–0086 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Ms. Judy Leung-Yee, First Coast Guard District, Project Officer, telephone 212–514–4336, email *Judy.K.Leung-Yee@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security

FR Federal Register
OMB Office of Management and Budget
NPRM Notice of Proposed Rulemaking (Advance, Supplemental)
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On March 15, 2019, the Coast Guard also published a temporary deviation with a request for comments (84 FR 9459), to test a proposed schedule. Five comments were received during the test period and those comments were addressed in the aforementioned NPRM.

On October 7, 2019, the Coast Guard published a notice of proposed rulemaking entitled ''Drawbridge Operation Regulation; Hackensack River, Little Snake Hill, NJ,'' in the **Federal Register** (84 FR 53350). In the NPRM, incorrect number of openings was provided. The correct number is provided below in Section III. We received three comments in response to the NPRM.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under the authority of 33 U.S.C. 499. The Amtrak Portal Bridge at mile 5.0 over the Hackensack River at Little Snake Hill, New Jersey, has a vertical clearance of 23 feet at mean high water and 28 feet at mean low water. Horizontal clearance is approximately 99 feet. The waterway users include recreational and commercial vessels, including tugboat/barge combinations.

The existing drawbridge operating regulations are listed at 33 CFR 117.723(e). In December of 2018, the owner of the bridge, National Railroad Passenger Corporation, requested a change to the drawbridge operation regulations because the volume of train traffic across the bridge during the peak commuting hours makes bridge openings impractical under the current schedule. As a result, bridge openings that occur during peak commuter train hours cause significant delays to commuter rail traffic. The owner proposed that the bridge opening schedule be revised so the bridge need not open for the passage of vessel traffic, Monday through Friday, from 5 a.m. to 10 a.m. and from 3 p.m. to 8 p.m. At all other times the bridge shall open on signal if at least 24 hour notice is given.

The Coast Guard reached out to the maritime stakeholders with the requested change proposed by the bridge owner. A stakeholder provided a general objection to the change in the original request.

In the NPRM, the Coast Guard mistakenly reported that there were three requests to open from March 14, 2019 through July 12, 2019. There were actually only two requests to open during this period.

IV. Discussion of Comments, Changes and the Final Rule

The Coast Guard provided 60 days for comment regarding this rule and three comments in the docket were received, with one comment received after the December 6, 2019, closing date. Two of comments supported the rulemaking but recommended greater advance notice (24 & 48 hours, respectively), increasing each peak commuting hour time periods by one hour and completely banning bridge openings during these commuter time periods. A third commenter recommended a four-hour advance notice for tide-restricted vessels. In addition, one commenter recommended changing the language from ''need not open'' to ''shall not open.'' The Coast Guard disagrees with these suggestions. As a result of the aforementioned reach out to maritime stakeholders, and in agreement with Amtrak, all concerned agreed a two-hour advance notice would be sufficient time for the bridge owner to assemble a team of technicians for the scheduled opening and address any mechanical and electrical issues that might arise. There is active commercial and recreational traffic on this waterway with the bridge logs indicating two requests to open from October 7, 2019, through December 6, 2019, during the NPRM comment period; therefore any permanent closure of the bridge is not an option. If the word ''need'' be replaced with ''shall,'' this would make passage prohibitive, due to the safety of navigation for vessels affected by tide influence and the permissibility of emergency vessels or vessels in an emergency situation (33 CFR 117.31) to pass. One commenter recommended permanently leaving the bridge closed with an agreement by Amtrak to replace it with a new fixed bridge with a vertical clearance of 25 feet. A Coast Guard Bridge Permit was issued to Amtrak approving a new fixed bridge with 50ft of vertical clearance.

There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

The final rule provides the draw need not open for the passage of vessel traffic from 5 a.m. to 10 a.m. and from 3 p.m. to 8 p.m. Additional bridge openings shall be provided for tide restricted commercial vessels between 7 a.m. and 8 a.m. and between 5 p.m. and 6 p.m., if at least a two-hour advance notice is given by calling the number posted at the bridge. At all other times the bridge shall open on signal if at least two-hour advance notice is given. It is the Coast Guard's opinion that this rule meets the reasonable needs of marine and rail traffic.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget (OMB) and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

The Coast Guard believes this rule is not a significant regulatory action. The bridge will still open for all vessel traffic after a two-hour advance notice is given, except during the morning and afternoon commuter rush hour periods, where a one-hour time period will allow passage of commercial vessels. The vertical clearance under the bridge in the closed position is relatively high enough to accommodate most vessel traffic during the time periods the draw is closed during the morning and evening commuter rush hours. We believe that this change to the drawbridge operation regulations at 33 CFR 117.723(e) will meet the reasonable needs of navigation.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comment from the Small Business Administration on this rule. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact

on a substantial number of small entities.

The bridge provides 23 feet of vertical clearance at mean high water that should accommodate all the present vessel traffic except deep draft vessels. The bridge will continue to open on signal for any vessel provided at least two-hour advance notice is given. While some owners or operators of vessels intending to transit the bridge may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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

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

C. Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Government

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f) andhave determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule promulgates the operating regulations or procedures for drawbridges. This action is categorically excluded from further review, under paragraph L49, of Chapter 3, Table 3–1 of the U.S. Coast Guard Environmental Planning Implementation Procedures.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are required for this rule.

G. Protest Activities

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

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 117.723(e) to read as follows:

§ 117.723 Hackensack River.

* * * * *

(e) The draw of the Amtrak Portal Bridge, mile 5.0, at Little Snake Hill, New Jersey, need not open for the passage of vessel traffic from 5 a.m. to 10 a.m. and from 3 p.m. to 8 p.m. Additional bridge openings shall be provided for tide restricted commercial vessels between 7 a.m. and 8 a.m. and between 5 p.m. and 6 p.m., if at least a two-hour advance notice is given by calling the number posted at the bridge. At all other times the bridge shall open on signal if at least two-hour advance notice is given.

* * * * *

Dated: January 30, 2020.

A.J. Tiongson,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 2020–02973 Filed 2–14–20; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2019–0462; FRL–10005–28–Region 4]

Air Plan Approval; Georgia: Revisions to Cross-State Air Pollution Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision submitted by the State of Georgia, through the Georgia Environmental Protection Division (GA EPD) of the Department of Natural Resources, via a letter dated July 31, 2018. Specifically, EPA is approving typographical changes to Georgia's SIP-approved regulations regarding its Cross-State Air Pollution Rule (CSAPR) state trading programs. This action is being approved pursuant to the Clean Air Act (CAA or Act) and its implementing regulations.

DATES: This rule will be effective March 19, 2020.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2019–0462. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Steven Scofield, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9034. Mr. Scofield can also be reached via electronic mail at *scofield.steve@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On October 15, 2019 (84 FR 55107), EPA proposed to approve into the Georgia SIP several changes to Georgia's air quality rule 391–3–1–.02, ''Provisions. Amended.'' GA EPD submitted a SIP revision through a letter dated July 31, 2018,[1] to EPA for review and approval that revises Georgia's SIP-approved rules regarding its CSAPR[2] state trading programs at Rule 391–3–1–.02(12)—''Cross State Air Pollution Rule NO_X Annual Trading Program,'' Rule 391–3–1–.02(13)—''Cross State Air Pollution Rule SO_2 Annual Trading Program,'' and Rule 391–3–1–.02(14)—''Cross State Air Pollution Rule NO_X Ozone Season Trading Program.'' The details of the Georgia submission and the rationale for EPA's action are explained in the proposed rulemaking. Comments on the proposed rulemaking were due on or before November 14, 2019. EPA did not receive any adverse comments on the proposed action. EPA is now taking final action to approve the above-referenced revisions.

II. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of Georgia Rule 391–3–1–.02(12)—''Cross State Air Pollution Rule NO_X Annual Trading Program,'' Rule 391–3–1–.02(13)—''Cross State Air Pollution Rule SO_2 Annual Trading Program,'' and Rule 391–3–1–.02(14)—''Cross State Air Pollution Rule NO_X Ozone Season Trading Program,'' State effective July 23, 2018. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the State implementation plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[3]

III. Final Action

EPA is approving the aforementioned changes to Georgia's SIP at Rule 391–3–1–.02(12)—''Cross State Air Pollution Rule NO_X Annual Trading Program,'' Rule 391–3–1–.02(13)—''Cross State Air Pollution Rule SO_2 Annual Trading Program,'' and Rule 391–3–1–.02(14)—''Cross State Air Pollution Rule NO_X Ozone Season Trading Program.'' These changes are consistent with the CAA.

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. *See* 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. 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 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

[1] EPA received the SIP revision on August 2, 2018. EPA received several other SIP revisions from Georgia through GA EPD's July 31, 2018, letter. These other revisions have been or will be addressed in separate EPA actions.

[2] CSAPR is a Federal rule that requires 27 Eastern states to limit their statewide emissions of sulfur dioxide (SO_2) and nitrogen oxides (NO_x) from electric generating units (EGUs) that significantly contribute to downwind nonattainment of the 1997 Annual fine particulate matter ($PM_{2.5}$) and 8-hour ozone national ambient air quality standards (NAAQS), 2006 24-hour $PM_{2.5}$ NAAQS, and the 2008 8-hour ozone NAAQS. Through its CSAPR rulemakings, EPA determined that air pollution transported from EGUs in Georgia would unlawfully affect other states' ability to attain or maintain the 1997 8-hour ozone NAAQS, the 1997 Annual $PM_{2.5}$ NAAQS, and the 2006 24-hour $PM_{2.5}$ NAAQS, and included Georgia in the CSAPR ozone season NO_X trading program and the annual SO_2 and NO_X trading programs. In 2017, EPA approved Georgia's State trading programs for annual NO_X, annual SO_2, and ozone season NO_X emissions and incorporated Georgia Rules 391–3–1–.02(12), .02(13), and .02(14) into the SIP. *See* 82 FR 47930 (October 13, 2017) for more information on CSAPR and Georgia's CSAPR state trading programs.

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

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

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

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. 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 CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 20, 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, Carbon moNO$_X$ide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: January 31, 2020.

Mary S. Walker,

Regional Administrator, Region 4.

40 CFR part 52 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 L—Georgia

■ 2. Section 52.570(c) is amended in the table under the heading ''391–3–1–.02(2) Emission Standards'' by revising the entries for ''391–3–1–.02(12)'', ''391–3–1–.02(13)'', and ''391–3–1–.02(14)'' to read as follows:

§ 52.570 Identification of plan.

* * * * *

(c) * * *

EPA APPROVED GEORGIA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	*
391–3–1–.02(2)	Emission Standards			
*	*	*	*	*
391–3–1–.02(12)	Cross State Air Pollution Rule NO$_X$ Annual Trading Program.	7/23/2018	2/18/2020, [Insert citation of publication].	
391–3–1–.02(13)	Cross State Air Pollution Rule SO$_2$ Annual Trading Program.	7/23/2018	2/18/2020, [Insert citation of publication].	
391–3–1–.02(14)	Cross State Air Pollution Rule NO$_X$ Ozone Season Trading Program.	7/23/2018	2/18/2020, [Insert citation of publication].	
*	*	*	*	*

* * * * *

[FR Doc. 2020–02605 Filed 2–14–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60, 61, and 63

[EPA–R09–OAR–2019–0632; FRL–10004–33–Region 9]

Delegation of New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants for the States of Arizona and Nevada

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to update the Code of Federal Regulations delegation tables to reflect the current delegation status of New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants in Arizona and Nevada.

DATES: This rule is effective on April 20, 2020 without further notice, unless EPA receives adverse comments by March 19, 2020. If we receive such comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that this direct final rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2019–0632 at *http://*

www.regulations.gov, or via email to *buss.jeffrey@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, 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, 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 *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Jeffrey Buss, EPA Region IX, (415) 947–4152, *buss.jeffrey@epa.gov.*

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

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I. Background

A. What is the purpose of this document?

Through this document, the EPA is accomplishing the following objectives:

(1) Update the delegation tables in the Code of Federal Regulations, title 40 (40 CFR), parts 60, 61, and 63 to provide an accurate listing of the delegated New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP); and

(2) Clarify those authorities that the EPA retains and are not granted to state or local agencies as part of NSPS or NESHAP delegation.

Update of Tables in the CFR

This action will update the delegation tables in 40 CFR parts 60, 61, and 63, to allow easier access by the public to the status of delegations in various state or local jurisdictions.

The updated delegation tables will include the delegations approved in response to recent requests, as well as those previously granted. The tables are shown at the end of this document.

Recent requests for delegation that will be incorporated into the updated 40 CFR parts 60, 61, and 63 tables are identified below. Each individual submittal identifies the specific NSPS and NESHAP for which delegation was requested. The requests have already been approved by letter and simply need to be included in the CFR tables.

Agency	Date of request	Date of approval by letter
Maricopa County Air Quality Department	January 18, 2018, December 6, 2018 and November 21, 2019.	September 7, 2018, May 20, 2019 and December 23, 2019.
Nevada Division of Environmental Protection	May 26, 2017 and March 29, 2019	July 26, 2017 and May 20, 2019.

B. Who is authorized to delegate these authorities?

Sections 111(c)(1) and 112(l) of the Clean Air Act, as amended in 1990, authorizes the Administrator to delegate his or her authority for implementing and enforcing standards in 40 CFR parts 60, 61, and 63.

C. What does delegation accomplish?

Delegation grants a state or local agency the primary authority to implement and enforce Federal standards. All required notifications and reports should be sent to the delegated state or local agency with a copy to EPA Region IX, as appropriate. Acceptance of delegation constitutes agreement by the state or local agency to follow 40 CFR parts 60, 61, and 63, and the EPA's test methods and continuous monitoring procedures.

D. What authorities are not delegated by the EPA?

In general, the EPA does not delegate to state or local agencies the authority to make decisions that are likely to be nationally significant or alter the stringency of the underlying standards. For a more detailed description of the authorities in 40 CFR parts 60 and 61 that are retained by the EPA, *see* 67 FR 20652 (April 26, 2002). For a more detailed description of the authorities in 40 CFR part 63 that are retained by the EPA, *see* 65 FR 55810 (September 14, 2000).

As additional assurance of national consistency, state and local agencies must send to EPA Region IX Enforcement Division's Air Section Chief a copy of any written decisions made pursuant to the following delegated authorities:

- Applicability determinations that state a source is not subject to a rule or requirement;
- approvals or determination of construction, reconstruction, or modification;
- minor or intermediate site-specific changes to test methods or monitoring requirements; or
- site-specific changes or waivers of performance testing requirements.

For decisions that require EPA review and approval (for example, major changes to monitoring requirements), the EPA intends to make determinations in a timely manner.

In some cases, the standards themselves specify that specific provisions cannot be delegated. State and local agencies should review each individual standard for this information.

E. Does the EPA keep some authority?

The EPA retains independent authority to enforce the standards and regulations of 40 CFR parts 60, 61, and 63.

II. EPA Action

This document serves to notify the public that the EPA is updating the 40 CFR parts 60, 61, and 63 tables for Arizona and Nevada to codify recent delegations of NSPS and NESHAP as authorized under Sections 111(c)(1) and 112(1)(l) of the Clean Air Act.

III. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve delegation requests that comply with the provisions of the Act and applicable Federal regulations. 42 U.S.C. Sections 7410(c) and 7412(l). Thus, in reviewing delegation 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 Order 12866 (58 FR 51735, October 4, 1993);
- 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 EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the delegation submissions are 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).

List of Subjects in 40 CFR Parts 60, 61, and 63

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: December 23, 2019.

Elizabeth J. Adams,

Director, Air and Radiation Division, Region IX.

For the reasons set out in the preamble, title 40, chapter I, of the Code of Federal Regulations is amended as follows:

PART 60—[AMENDED]

■ 1. The authority citation for part 60 continues to read as follows:

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

Subpart A—General Provisions

■ 2. Section 60.4 is amended by revising the tables in paragraphs (d)(1) and (4) to read as follows:

§ 60.4 Address.

* * * * *

(d) * * *

(1) * * *

TABLE 3 TO PARAGRAPH (d)(1)—DELEGATION STATUS FOR NEW SOURCE PERFORMANCE STANDARDS FOR ARIZONA

	Subpart	Air pollution control agency			
		Arizona DEQ	Maricopa County	Pima County	Pinal County
A	General Provisions	X	X	X	X
D	Fossil-Fuel Fired Steam Generators Constructed After August 17, 1971.	X	X	X	X
Da	Electric Utility Steam Generating Units Constructed After September 18, 1978.	X	X	X	X
Db	Industrial-Commercial-Institutional Steam Generating Units	X	X	X	X
Dc	Small Industrial-Commercial-Institutional Steam Generating Units.	X	X	X	X
E	Incinerators	X	X	X	X
Ea	Municipal Waste Combustors Constructed After December 20, 1989 and On or Before September 20, 1994.	X	X	X	X
Eb	Large Municipal Waste Combustors Constructed After September 20, 1994.	X	X	X	.....
Ec	Hospital/Medical/Infectious Waste Incinerators for Which Construction is Commenced After June 20, 1996.	X	X	X	.....
F	Portland Cement Plants	X	.....	X	X
G	Nitric Acid Plants	X	X	X	X
Ga	Nitric Acid Plants For Which Construction, Reconstruction or Modification Commenced After October 14, 2011.	.....	X	X	.....
H	Sulfuric Acid Plant	X	X	X	X
I	Hot Mix Asphalt Facilities	X	X	X	X
J	Petroleum Refineries	X	.....	X	X
Ja	Petroleum Refineries for Which Construction, Reconstruction, or Modification Commenced After May 14, 2007.	.....	.....	X	.....
K	Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction, or Modification Commenced After June 11, 1973, and Prior to May 19, 1978.	X	X	X	X
Ka	Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction, or Modification Commenced After May 18, 1978, and Prior to July 23, 1984.	X	X	X	X

TABLE 3 TO PARAGRAPH (d)(1)—DELEGATION STATUS FOR NEW SOURCE PERFORMANCE STANDARDS FOR ARIZONA—Continued

	Subpart	Air pollution control agency			
		Arizona DEQ	Maricopa County	Pima County	Pinal County
Kb	Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984.	X	X	X	X
L	Secondary Lead Smelters	X		X	X
M	Secondary Brass and Bronze Production Plants	X	X	X	X
N	Primary Emissions from Basic Oxygen Process Furnaces for Which Construction is Commenced After June 11, 1973.	X	X	X	X
Na	Secondary Emissions from Basic Oxygen Process Steelmaking Facilities for Which Construction is Commenced After January 20, 1983.	X	X	X	X
O	Sewage Treatment Plants	X	X	X	X
P	Primary Copper Smelters	X		X	X
Q	Primary Zinc Smelters	X		X	X
R	Primary Lead Smelters	X		X	X
S	Primary Aluminum Reduction Plants	X	X	X	X
T	Phosphate Fertilizer Industry: Wet Process Phosphoric Acid Plants.	X	X	X	X
U	Phosphate Fertilizer Industry: Superphosphoric Acid Plants.	X	X	X	X
V	Phosphate Fertilizer Industry: Diammonium Phosphate Plants.	X	X	X	X
W	Phosphate Fertilizer Industry: Triple Superphosphate Plants.	X	X	X	X
X	Phosphate Fertilizer Industry: Granular Triple Superphosphate Storage Facilities.	X	X	X	X
Y	Coal Preparation and Processing Plants	X	X	X	X
Z	Ferroalloy Production Facilities	X	X	X	X
AA	Steel Plants: Electric Arc Furnaces Constructed After October 21, 1974 and On or Before August 17, 1983.	X	X	X	X
AAa	Steel Plants: Electric Arc Furnaces and Argon-Oxygen Decarburization Vessels Constructed After August 7, 1983.	X	X	X	X
BB	Kraft Pulp Mills	X	X	X	X
BBa	Kraft Pulp Mill Sources for which Construction, Reconstruction or Modification Commenced after May 23, 2013.		X	X	
CC	Glass Manufacturing Plants	X	X	X	X
DD	Grain Elevators	X	X	X	X
EE	Surface Coating of Metal Furniture	X	X	X	X
FF	(Reserved).				
GG	Stationary Gas Turbines	X	X	X	X
HH	Lime Manufacturing Plants	X	X	X	X
KK	Lead-Acid Battery Manufacturing Plants	X	X	X	X
LL	Metallic Mineral Processing Plants	X	X	X	X
MM	Automobile and Light Duty Trucks Surface Coating Operations.	X	X	X	X
NN	Phosphate Rock Plants	X	X	X	X
PP	Ammonium Sulfate Manufacture	X	X	X	X
QQ	Graphic Arts Industry: Publication Rotogravure Printing	X	X	X	X
RR	Pressure Sensitive Tape and Label Surface Coating Operations.	X	X	X	X
SS	Industrial Surface Coating: Large Appliances	X	X	X	X
TT	Metal Coil Surface Coating	X	X	X	X
UU	Asphalt Processing and Asphalt Roofing Manufacture	X	X	X	X
VV	Equipment Leaks of VOC in the Synthetic Organic Industry Chemicals Manufacturing.	X	X	X	X
VVa	Equipment Leaks of VOC in the Synthetic Organic Industry for Which Construction, Reconstruction, or Chemicals Manufacturing Modification Commenced After November 7, 2006.	X	X	X	
WW	Beverage Can Surface Coating Industry	X	X	X	X
XX	Bulk Gasoline Terminals	X	X	X	X
AAA	New Residential Wood Heaters	X	X	X	X
BBB	Rubber Tire Manufacturing Industry	X	X	X	X
CCC	(Reserved).				

TABLE 3 TO PARAGRAPH (d)(1)—DELEGATION STATUS FOR NEW SOURCE PERFORMANCE STANDARDS FOR ARIZONA—Continued

	Subpart	Air pollution control agency			
		Arizona DEQ	Maricopa County	Pima County	Pinal County
DDD	Volatile Organic Compounds (VOC) Emissions from the Polymer Manufacturing Industry.	X	X	X	X
EEE	(Reserved).				
FFF	Flexible Vinyl and Urethane Coating and Printing	X	X	X	X
GGG	Equipment Leaks of VOC in Petroleum Refineries	X		X	X
GGGa	Equipment Leaks of VOC in Petroleum Refineries for Which Construction, Reconstruction, or Modification Commenced After November 7, 2006.	X		X	
HHH	Synthetic Fiber Production Facilities	X	X	X	X
III	Volatile Organic Compound (VOC) Emissions From the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Processes.	X	X	X	X
JJJ	Petroleum Dry Cleaners	X	X	X	X
KKK	Equipment Leaks of VOC From Onshore Natural Gas Processing Plants.	X	X	X	X
LLL	Onshore Natural Gas Processing: SO_2 Emissions	X	X	X	X
MMM	(Reserved).				
NNN	Volatile Organic Compound (VOC) Emissions From Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations.	X	X	X	X
OOO	Nonmetallic Mineral Processing Plants	X	X	X	X
PPP	Wool Fiberglass Insulation Manufacturing Plants	X	X	X	X
QQQ	VOC Emissions From Petroleum Refinery Wastewater Systems.	X		X	X
RRR	Volatile Organic Compound Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Reactor Processes.	X	X		
SSS	Magnetic Tape Coating Facilities	X	X	X	X
TTT	Industrial Surface Coating: Surface Coating of Plastic Parts for Business Machines.	X	X	X	X
UUU	Calciners and Dryers in Mineral Industries	X	X	X	
VVV	Polymeric Coating of Supporting Substrates Facilities	X	X	X	X
WWW	Municipal Solid Waste Landfills	X	X	X	
XXX	Municipal Solid Waste Landfills that Commenced Construction, Reconstruction, or Modification After July 17, 2014.		X		
AAAA	Small Municipal Waste Combustion Units for Which Construction is Commenced After August 30, 1999 or for Which Modification or Reconstruction is Commended After June 6, 2001.	X	X	X	
CCCC	Commercial and Industrial Solid Waste Incineration Units for Which Construction Is Commenced After November 30, 1999 or for Which Modification or Reconstruction Is Commenced on or After June 1, 2001.	X	X	X	
EEEE	Other Solid Waste Incineration Units for Which Construction is Commenced After December 9, 2004, or for Which Modification or Reconstruction is Commenced on or After June 16, 2006.	X	X	X	
GGGG	(Reserved).				
HHHH	(Reserved).				
IIII	Stationary Compression Ignition Internal Combustion Engines.	X	X	X	
JJJJ	Stationary Spark Ignition Internal Combustion Engines		X	X	
KKKK	Stationary Combustion Turbines	X	X	X	
LLLL	New Sewage Sludge Incineration Units			X	
MMMM	Emissions Guidelines and Compliance Times for Existing Sewage Sludge Incineration Units.	X			
OOOO	Crude Oil and Natural Gas Production, Transmission, and Distribution.		X	X	
OOOOa	Standards of Performance for Crude Oil and Natural Gas Facilities for Which Construction, Modification or Reconstruction Commenced After September 18, 2015.		X		
QQQQ	Standards of Performance for New Residential Hydronic Heaters and Forced-Air Furnaces.		X	X	
TTTT	Standards of Performance for Greenhouse Gas Emissions for Electric Generating Units.		X		

* * * * *

(4) * * *

TABLE 12 TO PARAGRAPH (d)(4)—DELEGATION STATUS FOR NEW SOURCE PERFORMANCE STANDARDS FOR NEVADA

	Subpart	Air pollution control agency		
		Nevada DEP	Clark County	Washoe County
A	General Provisions	X	X	X
Cf	Emission Guidelines and Compliance Times for Municipal Solid Waste Landfills.	X		
D	Fossil-Fuel Fired Steam Generators Constructed After August 17, 1971	X	X	X
Da	Electric Utility Steam Generating Units Constructed After September 18, 1978.	X	X	
Db	Industrial-Commercial-Institutional Steam Generating Units	X	X	
Dc	Small Industrial-Commercial-Institutional Steam Generating Units	X	X	
E	Incinerators	X	X	X
Ea	Municipal Waste Combustors Constructed After December 20, 1989 and On or Before September 20, 1994.	X	X	
Eb	Large Municipal Waste Combustors Constructed After September 20, 1994.	X	X	
Ec	Hospital/Medical/Infectious Waste Incinerators for Which Construction is Commenced After June 20, 1996.	X	X	
F	Portland Cement Plants	X	X	X
G	Nitric Acid Plants	X	X	
Ga	Nitric Acid Plants For Which Construction, Reconstruction or Modification Commenced After October 14, 2011.	X		
H	Sulfuric Acid Plant	X	X	
I	Hot Mix Asphalt Facilities	X	X	X
J	Petroleum Refineries	X	X	
Ja	Petroleum Refineries for Which Construction, Reconstruction, or Modification Commenced After May 14, 2007.	X		
K	Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction, or Modification Commenced After June 11, 1973, and Prior to May 19, 1978.	X	X	X
Ka	Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction, or Modification Commenced After May 18, 1978, and Prior to July 23, 1984.	X	X	X
Kb	Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984.	X	X	
L	Secondary Lead Smelters	X	X	X
M	Secondary Brass and Bronze Production Plants	X	X	
N	Primary Emissions from Basic Oxygen Process Furnaces for Which Construction is Commenced After June 11, 1973.	X	X	
Na	Secondary Emissions from Basic Oxygen Process Steelmaking Facilities for Which Construction is Commenced After January 20, 1983.	X	X	
O	Sewage Treatment Plants	X	X	X
P	Primary Copper Smelters	X	X	X
Q	Primary Zinc Smelters	X	X	X
R	Primary Lead Smelters	X	X	X
S	Primary Aluminum Reduction Plants	X	X	
T	Phosphate Fertilizer Industry: Wet Process Phosphoric Acid Plants		X	
U	Phosphate Fertilizer Industry: Superphosphoric Acid Plants		X	
V	Phosphate Fertilizer Industry: Diammonium Phosphate Plants		X	
W	Phosphate Fertilizer Industry: Triple Superphosphate Plants		X	
X	Phosphate Fertilizer Industry: Granular Triple Superphosphate Storage Facilities.		X	
Y	Coal Preparation and Processing Plants	X	X	X
Z	Ferroalloy Production Facilities	X	X	
AA	Steel Plants: Electric Arc Furnaces Constructed After October 21, 1974 and On or Before August 17, 1983.	X	X	
AAa	Steel Plants: Electric Arc Furnaces and Argon-Oxygen Decarburization Vessels Constructed After August 7, 1983.	X	X	
BB	Kraft Pulp Mills		X	
CC	Glass Manufacturing Plants	X	X	
DD	Grain Elevators	X	X	X
EE	Surface Coating of Metal Furniture	X	X	X
FF	(Reserved).			
GG	Stationary Gas Turbines	X	X	X
HH	Lime Manufacturing Plants	X	X	X
KK	Lead-Acid Battery Manufacturing Plants	X	X	X
LL	Metallic Mineral Processing Plants	X	X	X
MM	Automobile and Light Duty Trucks Surface Coating Operations	X	X	X

TABLE 12 TO PARAGRAPH (d)(4)—DELEGATION STATUS FOR NEW SOURCE PERFORMANCE STANDARDS FOR NEVADA—Continued

	Subpart	Air pollution control agency		
		Nevada DEP	Clark County	Washoe County
NN	Phosphate Rock Plants	X	X	X
PP	Ammonium Sulfate Manufacture	X	X	
QQ	Graphic Arts Industry: Publication Rotogravure Printing	X	X	X
RR	Pressure Sensitive Tape and Label Surface Coating Operations	X	X	
SS	Industrial Surface Coating: Large Appliances	X	X	X
TT	Metal Coil Surface Coating	X	X	X
UU	Asphalt Processing and Asphalt Roofing Manufacture	X	X	X
VV	Equipment Leaks of VOC in the Synthetic Organic Industry Chemicals Manufacturing.	X	X	X
VVa	Equipment Leaks of VOC in the Synthetic Organic Industry for Which Construction, Reconstruction, or Chemicals Manufacturing Modification Commenced After November 7, 2006.	X	X	
WW	Beverage Can Surface Coating Industry	X	X	
XX	Bulk Gasoline Terminals	X	X	
AAA	New Residential Wood Heaters		X	
BBB	Rubber Tire Manufacturing Industry	X	X	
CCC	(Reserved).			
DDD	Volatile Organic Compounds (VOC) Emissions from the Polymer Manufacturing Industry.	X	X	
EEE	(Reserved).			
FFF	Flexible Vinyl and Urethane Coating and Printing	X	X	
GGG	Equipment Leaks of VOC in Petroleum Refineries	X	X	
GGGa	Equipment Leaks of VOC in Petroleum Refineries for Which Construction, Reconstruction, or Modification Commenced After November 7, 2006.	X	X	
HHH	Synthetic Fiber Production Facilities	X	X	
III	Volatile Organic Compound (VOC) Emissions From the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Processes.	X	X	
JJJ	Petroleum Dry Cleaners	X	X	X
KKK	Equipment Leaks of VOC From Onshore Natural Gas Processing Plants	X	X	
LLL	Onshore Natural Gas Processing: SO_2 Emissions	X	X	
MMM	(Reserved).			
NNN	Volatile Organic Compound (VOC) Emissions From Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations.	X	X	
OOO	Nonmetallic Mineral Processing Plants	X	X	
PPP	Wool Fiberglass Insulation Manufacturing Plants	X	X	
QQQ	VOC Emissions From Petroleum Refinery Wastewater Systems	X	X	
RRR	Volatile Organic Compound Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Reactor Processes.	X	X	
SSS	Magnetic Tape Coating Facilities	X	X	
TTT	Industrial Surface Coating: Surface Coating of Plastic Parts for Business Machines.	X	X	X
UUU	Calciners and Dryers in Mineral Industries	X	X	X
VVV	Polymeric Coating of Supporting Substrates Facilities	X	X	X
WWW	Municipal Solid Waste Landfills	X	X	X
XXX	Municipal Solid Waste Landfills that Commenced Construction, Reconstruction, or Modification after July 17, 2014.	X		
AAAA	Small Municipal Waste Combustion Units for Which Construction is Commenced After August 30, 1999 or for Which Modification or Reconstruction is Commended After June 6, 2001.	X	X	X
CCCC	Commercial and Industrial Solid Waste Incineration Units for Which Construction Is Commenced After November 30, 1999 or for Which Modification or Reconstruction Is Commenced on or After June 1, 2001.	X	X	X
EEEE	Other Solid Waste Incineration Units for Which Construction is Commenced After December 9, 2004, or for Which Modification or Reconstruction is Commenced on or After June 16, 2006.	X	X	X
GGGG	(Reserved).			
HHHH	(Reserved).			
IIII	Stationary Compression Ignition Internal Combustion Engines	X	X	X
JJJJ	Stationary Spark Ignition Internal Combustion Engines	X	X	X
KKKK	Stationary Combustion Turbines	X	X	X
LLLL	New Sewage Sludge Incineration Units		X	
OOOO	Crude Oil and Natural Gas Production, Transmission, and Distribution	X		

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PART 61—[AMENDED]

■ 3. The authority citation for part 61 continues to read as follows:

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

Subpart A—General Provisions

■ 4. Section 61.04 is amended by revising the table in paragraphs (c)(9)(i) and (iv) to read as follows:

§ 61.04 Address.

* * * * *

(c) * * *

(9) * * *

(i) * * *

TABLE 6 TO PARAGRAPH (c)(9)(i)—DELEGATION STATUS FOR NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR ARIZONA

	Subpart	Air pollution control agency			
		Arizona DEQ	Maricopa County	Pima County	Pinal County
A	General Provisions	X	X	X	X
B	Radon Emissions From Underground Uranium Mines				
C	Beryllium	X	X	X	X
D	Beryllium Rocket Motor Firing	X	X	X	X
E	Mercury	X	X	X	X
F	Vinyl Chloride	X	X	X	X
G	(Reserved)				
H	Emissions of Radionuclides Other Than Radon From Department of Energy Facilities.				
I	Radionuclide Emissions From Federal Facilities Other Than Nuclear Regulatory Commission Licensees and Not Covered by Subpart H.				
J	Equipment Leaks (Fugitive Emission Sources) of Benzene	X	X	X	X
K	Radionuclide Emissions From Elemental Phosphorus Plants.				
L	Benzene Emissions from Coke By-Product Recovery Plants.	X	X	X	X
M	Asbestos	X	X	X	X
N	Inorganic Arsenic Emissions From Glass Manufacturing Plants.	X	X	X	
O	Inorganic Arsenic Emissions From Primary Copper Smelters.	X		X	
P	Inorganic Arsenic Emissions From Arsenic Trioxide and Metallic Arsenic Production Facilities.	X	X		
Q	Radon Emissions From Department of Energy Facilities				
R	Radon Emissions From Phosphogypsum Stacks				
S	(Reserved)				
T	Radon Emissions From the Disposal of Uranium Mill Tailings.				
U	(Reserved)				
V	Equipment Leaks (Fugitive Emission Sources)	X	X	X	X
W	Radon Emissions From Operating Mill Tailings				
X	(Reserved)				
Y	Benzene Emissions From Benzene Storage Vessels	X	X	X	X
Z–AA	(Reserved)				
BB	Benzene Emissions From Benzene Transfer Operations	X	X	X	X
CC–EE	(Reserved)				
FF	Benzene Waste Operations	X	X	X	X

* * * * *

(iv) * * *

TABLE 19—TO PARAGRAPH (c)(9)(iv)—DELEGATION STATUS FOR NATIONAL EMISSIONS STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR NEVADA

	Subpart	Air pollution control agency		
		Nevada DEP	Clark County	Washoe County
A	General Provisions	X	X	
B	Radon Emissions From Underground Uranium Mines			
C	Beryllium	X	X	X
D	Beryllium Rocket Motor Firing	X	X	
E	Mercury	X	X	
F	Vinyl Chloride	X	X	
G	(Reserved)			
H	Emissions of Radionuclides Other Than Radon From Department of Energy Facilities.	X		

TABLE 19—TO PARAGRAPH (c)(9)(iv)—DELEGATION STATUS FOR NATIONAL EMISSIONS STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR NEVADA—Continued

	Subpart	Air pollution control agency		
		Nevada DEP	Clark County	Washoe County
I	Radionuclide Emissions From Federal Facilities Other Than Nuclear Regulatory Commission Licensees and Not Covered by Subpart H.	X		
J	Equipment Leaks (Fugitive Emission Sources) of Benzene	X	X	
K	Radionuclide Emissions From Elemental Phosphorus Plants	X		
L	Benzene Emissions from Coke By-Product Recovery Plants	X	X	
M	Asbestos		X	X
N	Inorganic Arsenic Emissions From Glass Manufacturing Plants	X	X	
O	Inorganic Arsenic Emissions From Primary Copper Smelters	X	X	
P	Inorganic Arsenic Emissions From Arsenic Trioxide and Metallic Arsenic Production Facilities.	X	X	
Q	Radon Emissions From Department of Energy Facilities			
R	Radon Emissions From Phosphogypsum Stacks			
S	(Reserved)			
T	Radon Emissions From the Disposal of Uranium Mill Tailings			
U	(Reserved)			
V	Equipment Leaks (Fugitive Emission Sources)	X	X	
W	Radon Emissions From Operating Mill Tailings			
X	(Reserved)			
Y	Benzene Emissions From Benzene Storage Vessels	X	X	
Z–AA	(Reserved)			
BB	Benzene Emissions From Benzene Transfer Operations	X	X	
CC–EE	(Reserved)			
FF	Benzene Waste Operations	X	X	

* * * * *

PART 63—[AMENDED]

■ 5. The authority citation for part 63 continues to read as follows:

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

Subpart E—Approval of State Programs and Delegation of Federal Authorities

■ 6. Section 63.99 is amended by revising the table in paragraphs (a)(3)(i) and (a)(29)(i) to read as follows:

§ 63.99 Delegated Federal authorities.

(a) * * *

(3) * * *

(i) * * *

TABLE 3 TO PARAGRAPH (A)(3)(I)—DELEGATION STATUS FOR PART 63 STANDARDS—ARIZONA

Subpart	Description	ADEQ [1]	MCAQD [2]	PDEQ [3]	PCAQCD [4]	GRIC [5]
A	General Provisions	X	X	X	X	X
F	Synthetic Organic Chemical Manufacturing Industry.	X	X	X	X	X
G	Synthetic Organic Chemical Manufacturing Industry: Process Vents, Storage Vessels, Transfer Operations, and Wastewater.	X	X	X	X	X
H	Organic Hazardous Air Pollutants: Equipment Leaks.	X	X	X	X	X
I	Organic Hazardous Air Pollutants: Certain Processes Subject to the Negotiated Regulation for Equipment Leaks.	X	X	X	X	X
J	Polyvinyl Chloride and Copolymers Production.	X	X	X		X
L	Coke Oven Batteries	X	X	X	X	X
M	Perchloroethylene Dry Cleaning	X	X	X	X	X
N	Hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks.	X	X	X	X	X
O	Ethylene Oxide Sterilization Facilities	X	X	X	X	X
Q	Industrial Process Cooling Towers	X	X	X	X	X
R	Gasoline Distribution Facilities	X	X	X	X	X
S	Pulp and Paper	X	X	X		X
T	Halogenated Solvent Cleaning	X	X	X	X	X
U	Group I Polymers and Resins	X	X	X	X	X
W	Epoxy Resins Production and Non-Nylon Polyamides Production.	X	X	X	X	X
X	Secondary Lead Smelting	X		X	X	X

TABLE 3 TO PARAGRAPH (A)(3)(I)—DELEGATION STATUS FOR PART 63 STANDARDS—ARIZONA—Continued

Subpart	Description	ADEQ [1]	MCAQD [2]	PDEQ [3]	PCAQCD [4]	GRIC [5]
Y	Marine Tank Vessel Loading Operations.		X			X
AA	Phosphoric Acid Manufacturing Plants	X	X	X		X
BB	Phosphate Fertilizers Production Plants.	X	X	X		X
CC	Petroleum Refineries	X		X	X	X
DD	Off-Site Waste and Recovery Operations.	X	X	X	X	X
EE	Magnetic Tape Manufacturing Operations.	X	X	X	X	X
GG	Aerospace Manufacturing and Rework Facilities.	X	X	X	X	X
HH	Oil and Natural Gas Production Facilities.	X	X	X		X
II	Shipbuilding and Ship Repair (Surface Coating).					X
JJ	Wood Furniture Manufacturing Operations.	X	X	X	X	X
KK	Printing and Publishing Industry	X	X	X	X	X
LL	Primary Aluminum Reduction Plants	X	X	X		X
MM	Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills.	X	X	X		X
NN	Wool Fiberglass Manufacturing at Area Sources.		X			
OO	Tanks—Level 1	X	X	X	X	X
PP	Containers	X	X	X	X	X
QQ	Surface Impoundments	X	X	X	X	X
RR	Individual Drain Systems	X	X	X	X	X
SS	Closed Vent Systems, Control Devices, Recovery Devices and Routing to a Fuel Gas System or a Process.	X	X	X		X
TT	Equipment Leaks—Control Level 1	X	X	X		X
UU	Equipment Leaks—Control Level 2	X	X	X		X
VV	Oil-Water Separators and Organic-Water Separators.	X	X	X	X	X
WW	Storage Vessels (Tanks)—Control Level 2.	X	X	X		X
XX	Ethylene Manufacturing Process Units: Heat Exchange Systems and Waste Operations.	X	X	X		X
YY	Generic MACT Standards	X	X	X		X
CCC	Steel Pickling	X	X	X		X
DDD	Mineral Wool Production	X	X	X		X
EEE	Hazardous Waste Combustors	X	X	X		X
GGG	Pharmaceuticals Production	X	X	X		X
HHH	Natural Gas Transmission and Storage Facilities.	X	X	X		X
III	Flexible Polyurethane Foam Production.	X	X	X		X
JJJ	Group IV Polymers and Resins	X	X	X	X	X
LLL	Portland Cement Manufacturing Industry.	X		X		X
MMM	Pesticide Active Ingredient Production	X	X	X		X
NNN	Wool Fiberglass Manufacturing	X	X	X		X
OOO	Manufacture of Amino/Phenolic Resins	X	X	X		X
PPP	Polyether Polyols Production	X	X	X		X
QQQ	Primary Copper Smelting	X		X		X
RRR	Secondary Aluminum Production	X	X	X		X
TTT	Primary Lead Smelting	X		X		X
UUU	Petroleum Refineries: Catalytic Cracking, Catalytic Reforming, and Sulfur Recovery Units.	X		X		X
VVV	Publicly Owned Treatment Works	X	X	X		X
XXX	Ferroalloys Production	X	X	X		X
AAAA	Municipal Solid Waste Landfills	X	X	X		X
CCCC	Manufacturing of Nutritional Yeast	X	X	X		X
DDDD	Plywood and Composite Wood Products.	X	X	X		X

TABLE 3 TO PARAGRAPH (A)(3)(I)—DELEGATION STATUS FOR PART 63 STANDARDS—ARIZONA—Continued

Subpart	Description	ADEQ [1]	MCAQD [2]	PDEQ [3]	PCAQCD [4]	GRIC [5]
EEEE	Organic Liquids Distribution (non-gasoline).	X	X	X		X
FFFF	Miscellaneous Organic Chemical Manufacturing.	X	X	X		X
GGGG	Solvent Extraction for Vegetable Oil Production.	X	X	X		X
HHHH	Wet-Formed Fiberglass Mat Production.	X	X	X		X
IIII	Surface Coating of Automobiles and Light-Duty Trucks.	X	X			X
JJJJ	Paper and Other Web Coating	X	X	X		X
KKKK	Surface Coating of Metal Cans	X	X	X		X
MMMM	Miscellaneous Metal Parts and Products.	X	X	X		X
NNNN	Large Appliances	X	X	X		X
OOOO	Printing, Coating, and Dyeing of Fabrics and Other Textiles.	X	X	X		X
PPPP	Surface Coating of Plastic Parts and Products.	X	X			X
QQQQ	Wood Building Products	X	X	X		X
RRRR	Surface Coating of Metal Furniture	X	X	X		X
SSSS	Surface Coating of Metal Coil	X	X	X		X
TTTT	Leather Finishing Operations	X	X	X		X
UUUU	Cellulose Products Manufacturing	X	X	X		X
VVVV	Boat Manufacturing	X	X	X		X
WWWW	Reinforced Plastics Composites Production.	X	X	X		X
XXXX	Tire Manufacturing	X	X	X		X
YYYY	Stationary Combustion Turbines	X	X	X		X
ZZZZ	Stationary Reciprocating Internal Combustion Engines.	X	X			X
AAAAA	Lime Manufacturing Plants	X	X	X		X
BBBBB	Semiconductor Manufacturing	X	X	X		X
CCCCC	Coke Oven: Pushing, Quenching and Battery Stacks.	X	X	X		X
DDDDD	Industrial, Commercial, and Institutional Boiler and Process Heaters.	X	X			X
EEEEE	Iron and Steel Foundries	X	X	X		X
FFFFF	Integrated Iron and Steel	X	X	X		X
GGGGG	Site Remediation	X	X	X		X
HHHHH	Miscellaneous Coating Manufacturing	X	X	X		X
IIIII	Mercury Emissions from Mercury Cell Chlor-Alkali Plants.	X	X	X		X
JJJJJ	Brick and Structural Clay Products Manufacturing.	X	X	X		X
KKKKK	Clay Ceramics Manufacturing	X	X	X		X
LLLLL	Asphalt Roofing and Processing	X	X	X		X
MMMMM	Flexible Polyurethane Foam Fabrication Operation.	X	X	X		X
NNNNN	Hydrochloric Acid Production	X	X	X		X
PPPPP	Engine Test Cells/Stands	X	X	X		X
QQQQQ	Friction Products Manufacturing	X	X	X		X
RRRRR	Taconite Iron Ore Processing	X	X	X		X
SSSSS	Refractory Products Manufacturing	X	X	X		X
TTTTT	Primary Magnesium Refining	X	X	X		X
UUUUU	Coal and Oil-Fired Electric Utility Steam Generating Units.			X		
WWWWW	Hospital Ethylene Oxide Sterilizers		X	X		
YYYYY	Area Sources: Electric Arc Furnace Steelmaking Facilities.		X	X		
ZZZZZ	Iron and Steel Foundries Area Sources		X	X		
BBBBBB	Gasoline Distribution Bulk Terminals, Bulk Plants, and Pipeline Facilities.		X	X		
CCCCCC	Gasoline Dispensing Facilities		X	X		
DDDDDD	Polyvinyl Chloride and Copolymers Production Area Sources.		X	X		
EEEEEE	Primary Copper Smelting Area Sources.			X		
FFFFFF	Secondary Copper Smelting Area Sources.			X		

TABLE 3 TO PARAGRAPH (A)(3)(I)—DELEGATION STATUS FOR PART 63 STANDARDS—ARIZONA—Continued

Subpart	Description	ADEQ [1]	MCAQD [2]	PDEQ [3]	PCAQCD [4]	GRIC [5]
GGGGGG	Primary Nonferrous Metals Area Sources—Zinc, Cadmium, and Beryllium.		X	X		
HHHHHH	Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources.		X	X		
JJJJJJ	Industrial, Commercial, and Institutional Boilers and Process Heaters—Area Sources.		X	X		
LLLLLL	Acrylic and Modacrylic Fibers Production Area Sources.		X	X		
MMMMMM	Carbon Black Production Area Sources.		X	X		
NNNNNN	Chemical Manufacturing Area Sources: Chromium Compounds.		X	X		
OOOOOO	Flexible Polyurethane Foam Production and Fabrication Area Sources.		X	X		
PPPPPP	Lead Acid Battery Manufacturing Area Sources.		X	X		
QQQQQQ	Wood Preserving Area Sources		X	X		
RRRRRR	Clay Ceramics Manufacturing Area Sources.		X	X		
SSSSSS	Glass Manufacturing Area Sources		X	X		
TTTTTT	Secondary Nonferrous Metals Processing Area Sources.		X	X		
VVVVVV	Chemical Manufacturing Industry—Area Sources.		X	X		
WWWWWW	Area Source Standards for Plating and Polishing Operations.		X	X		
XXXXXX	Area Source Standards for Nine Metal Fabrication and Finishing Source Categories.		X	X		
YYYYYY	Area Sources: Ferroalloys Production Facilities.		X	X		
ZZZZZZ	Area Source Standards for Aluminum, Copper, and Other Nonferrous Foundries.		X	X		
AAAAAAA	Asphalt Processing and Asphalt Roofing Manufacturing—Area Sources.		X	X		
BBBBBBB	Chemical Preparations Industry—Area Sources.		X	X		
CCCCCCC	Paint and Allied Products Manufacturing—Area Sources.		X	X		
DDDDDDD	Prepared Feeds Manufacturing—Area Sources.		X	X		
EEEEEEE	Gold Mine Ore Processing and Production—Area Sources.		X	X		
HHHHHHH	Polyvinyl Chloride and Copolymers Production.		X	X		

[1] Arizona Department of Environmental Quality.
[2] Maricopa County Air Quality Department.
[3] Pima County Department of Environmental Quality.
[4] Pinal County Air Quality Control District.
[5] Gila River Indian Community Department of Environmental Quality. This table includes the GRIC DEQ only for purposes of identifying all state, local, and tribal agencies responsible for implementing part 63 standards within the geographical boundaries of the State of Arizona and does not establish any state regulatory authority in Indian country.

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(29) * * *

(i) * * *

TABLE 11 TO PARAGRAPH (a)(29)(i)—DELEGATION STATUS FOR PART 63 STANDARDS—NEVADA

Subpart	Description	NDEP [1]	Washoe [2]	Clark [3]
A	General Provisions	X	X	X
F	Synthetic Organic Chemical Manufacturing Industry	X		X
G	Synthetic Organic Chemical Manufacturing Industry: Process Vents, Storage Vessels, Transfer Operations, and Wastewater.	X		X
H	Organic Hazardous Air Pollutants: Equipment Leaks	X		X

TABLE 11 TO PARAGRAPH (a)(29)(i)—DELEGATION STATUS FOR PART 63 STANDARDS—NEVADA—Continued

Subpart	Description	NDEP [1]	Washoe [2]	Clark [3]
I	Organic Hazardous Air Pollutants: Certain Processes Subject to the Negotiated Regulation for Equipment Leaks.	X		X
J	Polyvinyl Chloride and Copolymers Production	X		X
L	Coke Oven Batteries	X		X
M	Perchloroethylene Dry Cleaning	X	X	X
N	Hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks.	X	X	X
O	Ethylene Oxide Sterilization Facilities	X	X	X
Q	Industrial Process Cooling Towers	X		X
R	Gasoline Distribution Facilities	X	X	X
S	Pulp and Paper	X		X
T	Halogenated Solvent Cleaning	X	X	X
U	Group I Polymers and Resins	X		X
W	Epoxy Resins Production and Non-Nylon Polyamides Production	X		X
X	Secondary Lead Smelting	X		X
Y	Marine Tank Vessel Loading Operations	X		
AA	Phosphoric Acid Manufacturing Plants			X
BB	Phosphate Fertilizers Production Plants			X
CC	Petroleum Refineries	X		X
DD	Off-Site Waste and Recovery Operations			X
EE	Magnetic Tape Manufacturing Operations	X		X
GG	Aerospace Manufacturing and Rework Facilities			X
HH	Oil and Natural Gas Production Facilities	X		X
II	Shipbuilding and Ship Repair (Surface Coating)	X		X
JJ	Wood Furniture Manufacturing Operations	X		X
KK	Printing and Publishing Industry	X	X	X
LL	Primary Aluminum Reduction Plants			X
MM	Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills.			X
OO	Tanks—Level 1	X		X
PP	Containers	X		X
QQ	Surface Impoundments	X		X
RR	Individual Drain Systems	X		X
SS	Closed Vent Systems, Control Devices, Recovery Devices and Routing to a Fuel Gas System or a Process.	X		X
TT	Equipment Leaks—Control Level 1	X		X
UU	Equipment Leaks—Control Level 2	X		X
VV	Oil-Water Separators and Organic-Water Separators	X		X
WW	Storage Vessels (Tanks)—Control Level 2	X		X
XX	Ethylene Manufacturing Process Units: Heat Exchange Systems and Waste Operations.	X		X
YY	Generic MACT Standards	X		X
CCC	Steel Pickling	X		X
DDD	Mineral Wool Production			X
EEE	Hazardous Waste Combustors	X		X
GGG	Pharmaceuticals Production	X		X
HHH	Natural Gas Transmission and Storage Facilities	X		X
III	Flexible Polyurethane Foam Production	X		X
JJJ	Group IV Polymers and Resins	X		X
LLL	Portland Cement Manufacturing Industry	X		X
MMM	Pesticide Active Ingredient Production	X		X
NNN	Wool Fiberglass Manufacturing			X
OOO	Manufacture of Amino/Phenolic Resins	X		X
PPP	Polyether Polyols Production	X		X
QQQ	Primary Copper Smelting	X		X
RRR	Secondary Aluminum Production			X
TTT	Primary Lead Smelting	X		X
UUU	Petroleum Refineries: Catalytic Cracking, Catalytic Reforming, and Sulfur Recovery Units.	X		X
VVV	Publicly Owned Treatment Works	X	X	X
XXX	Ferroalloys Production			X
AAAA	Municipal Solid Waste Landfills	X		X
CCCC	Manufacturing of Nutritional Yeast			X
DDDD	Plywood and Composite Wood Products	X		X
EEEE	Organic Liquids Distribution (non-gasoline)	X	X	X
FFFF	Miscellaneous Organic Chemical Manufacturing	X		X
GGGG	Solvent Extraction for Vegetable Oil Production	X		X
HHHH	Wet-Formed Fiberglass Mat Production	X		X
IIII	Surface Coating of Automobiles and Light-Duty Trucks	X		X
JJJJ	Paper and Other Web Coating	X		X
KKKK	Surface Coating of Metal Cans	X		X
MMMM	Miscellaneous Metal Parts and Products	X		X

TABLE 11 TO PARAGRAPH (a)(29)(i)—DELEGATION STATUS FOR PART 63 STANDARDS—NEVADA—Continued

Subpart	Description	NDEP [1]	Washoe [2]	Clark [3]
NNNN	Large Appliances	X		X
OOOO	Printing, Coating, and Dyeing of Fabrics and Other Textiles	X		X
PPPP	Surface Coating of Plastic Parts and Products	X		X
QQQQ	Wood Building Products	X		X
RRRR	Surface Coating of Metal Furniture	X		X
SSSS	Surface Coating of Metal Coil	X		X
TTTT	Leather Finishing Operations	X		X
UUUU	Cellulose Products Manufacturing	X		X
VVVV	Boat Manufacturing	X		X
WWWW	Reinforced Plastics Composites Production	X	X	X
XXXX	Tire Manufacturing	X		X
YYYY	Stationary Combustion Turbines	X		X
ZZZZ	Stationary Reciprocating Internal Combustion Engines	X	X	X
AAAAA	Lime Manufacturing Plants	X		X
BBBBB	Semiconductor Manufacturing	X		X
CCCCC	Coke Oven: Pushing, Quenching and Battery Stacks	X		X
DDDDD	Industrial, Commercial, and Institutional Boiler and Process Heaters	X		X
EEEEE	Iron and Steel Foundries	X		X
FFFFF	Integrated Iron and Steel	X		X
GGGGG	Site Remediation	X		X
HHHHH	Miscellaneous Coating Manufacturing	X		X
IIIII	Mercury Emissions from Mercury Cell Chlor-Alkali Plants			X
JJJJJ	Brick and Structural Clay Products Manufacturing	X		X
KKKKK	Clay Ceramics Manufacturing	X		X
LLLLL	Asphalt Roofing and Processing	X		X
MMMMM	Flexible Polyurethane Foam Fabrication Operation	X		X
NNNNN	Hydrochloric Acid Production	X		X
PPPPP	Engine Test Cells/Stands	X		X
QQQQQ	Friction Products Manufacturing	X		X
RRRRR	Taconite Iron Ore Processing			X
SSSSS	Refractory Products Manufacturing	X		X
TTTTT	Primary Magnesium Refining			X
UUUUU	Coal and Oil-Fired Electric Utility Steam Generating Units	X		
WWWWW	Hospital Ethylene Oxide Sterilizers	X	X	X
YYYYY	Electric Arc Furnace Steelmaking Facilities (area sources)			X
ZZZZZ	Iron and Steel Foundries Area Sources	X		X
BBBBBB	Gasoline Distribution Bulk Terminals, Bulk Plants and Pipeline Facilities	X	X	X
CCCCCC	Gasoline Dispensing Facilities	X	X	X
DDDDDD	Polyvinyl Chloride and Copolymers Production Area Sources	X		X
EEEEEE	Primary Copper Smelting Area Sources	X		X
FFFFFF	Secondary Copper Smelting Area Sources	X		X
GGGGGG	Primary Nonferrous Metals Area Sources—Zinc, Cadmium, and Beryllium	X		X
HHHHHH	Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources.	X	X	X
JJJJJJ	Industrial, Commercial, and Institutional Boilers and Process Heaters—Area Sources.	X		
LLLLLL	Acrylic and Modacrylic Fibers Production Area Sources	X		X
MMMMMM	Carbon Black Production Area Sources	X		X
NNNNNN	Chemical Manufacturing Area Sources: Chromium Compounds	X		X
OOOOOO	Flexible Polyurethane Foam Production and Fabrication Area Sources	X	X	X
PPPPPP	Lead Acid Battery Manufacturing Area Sources	X		X
QQQQQQ	Wood Preserving Area Sources	X		X
RRRRRR	Clay Ceramics Manufacturing Area Sources	X		X
SSSSSS	Glass Manufacturing Area Sources	X		X
TTTTTT	Secondary Nonferrous Metals Processing Area Sources	X		X
VVVVVV	Chemical Manufacturing Industry—Area Sources	X		X
WWWWWW	Area Source Standards for Plating and Polishing Operations	X	X	X
XXXXXX	Area Source Standards for Nine Metal Fabrication and Finishing Source Categories.	X	X	X
YYYYYY	Area Sources: Ferroalloys Production Facilities			X
ZZZZZZ	Area Source Standards for Aluminum, Copper, and Other Nonferrous Foundries.	X		X
AAAAAAA	Asphalt Processing and Asphalt Roofing Manufacturing—Area Sources	X		X
BBBBBBB	Chemical Preparations Industry—Area Sources	X		X
CCCCCCC	Paint and Allied Products Manufacturing—Area Sources	X		X
DDDDDDD	Prepared Feeds Manufacturing—Area Sources			X
EEEEEEE	Gold Mine Ore Processing and Production—Area Sources	X		X

[1] Nevada Division of Environmental Protection.
[2] Washoe County District Health Department, Air Quality Management Division.
[3] Clark County, Department of Air Quality.

* * * * *

[FR Doc. 2020–01730 Filed 2–14–20; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No.: 200212–0053]

RIN 0648–XX037

Fisheries of the Northeastern United States; Blueline Tilefish Fishery; 2020 Specifications

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

ACTION: Final rule.

SUMMARY: We are implementing 2020 specifications for the Mid-Atlantic blueline tilefish fishery, including the annual catch and total allowable landings limits. This action establishes allowable harvest levels and other management measures to prevent overfishing, consistent with the Magnuson-Stevens Fishery Conservation and Management Act and the Tilefish Fishery Management Plan.

DATES: Effective February 18, 2020, through December 31, 2020.

FOR FURTHER INFORMATION CONTACT: Laura Hansen, Fishery Management Specialist, 978–281–9225.

SUPPLEMENTARY INFORMATION:

Background

The Mid-Atlantic Fishery Management Council manages the blueline tilefish fishery north of the Virginia/North Carolina border under the Tilefish Fishery Management Plan (FMP), which outlines the Council's process for setting annual specifications. Regulations implementing the Tilefish FMP appear at 50 CFR part 648, subparts A and N, which require the Council to recommend acceptable biological catch (ABC), annual catch limit (ACL), annual catch target (ACT), total allowable landings (TAL), and other management measures, for up to 3 years at a time. On November 18, 2018, we proposed 2019 specifications for the blueline tilefish fishery and announced projected specifications for 2020 and 2021 based on Council recommendations (83 FR 58219). Public comment was accepted through December 4, 2018. We published a final rule implementing the 2019 specifications on February 12, 2019 (84 FR 3341).

At the end of each fishing year, we evaluate available catch information and determine if the ACL has been exceeded. If the ACL is exceeded, the regulations at 50 CFR 648.293 require a pound-for-pound reduction in a subsequent fishing year. During fishing year 2019, there were no annual catch limit or total allowable landings overages, nor is there any new biological information that would require altering the projected 2020 specifications. As a result, we are announcing the final specifications for fishing year 2020, as projected in the final rule implementing 2019 specifications (See Table 1).

TABLE 1—SUMMARY OF BLUELINE TILEFISH SPECIFICATIONS

Specifications	2020
ABC—North of NC/VA line	100,520 lb (45.6 mt)
Recreational ACL	73,380 (33.3 mt)
Commercial ACL	27,140 lb (12.3 mt)
Recreational TAL	71,912 lb (32.6 mt)
Commercial TAL	26,869 lb (12.2 mt)

All other management measures in the blueline tilefish fishery will remain unchanged for the 2020 fishing year.

The FMP allows for the previous year's specifications to remain in place until replaced by a subsequent specifications action (rollover provision). As a result, the 2019 specifications remain in effect until replaced by the 2020 specifications included in this rule.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this rule is consistent with the Tilefish FMP, other provisions of the Magnuson-Stevens Act, and other applicable laws.

The Assistant Administrator for Fisheries, NOAA finds it is impracticable, unnecessary, and contrary to the public interest to provide for prior notice and an opportunity for public comment, under to authority at U.S.C. 553(b)(B). The proposed rule for 2019–2021 specifications (83 FR 58219, November 18, 2018) provided the public with the opportunity to comment on the specifications for 2019, and projected 2020 and 2021 specifications. The specifications for fishing year 2020 remain the same as projected in the specifications rulemaking. All comments received were addressed in the final rule (84 FR 3341).

Similarly, the need to implement these measures in a timely manner for the start of the blueline tilefish fishing year, constitutes good cause under authority contained in 5 U.S.C. 553(d)(3), to establish an effective date less than 30 days after date of publication. The public and fishing industry participants expect this action because we previously alerted the public in the proposed and final rules that we would conduct this review in interim years of the status quo multi-year specifications and announce the final quota.

This final rule is exempt from review under Executive Order 12866 because this action contains no implementing regulations.

This final rule does not duplicate, conflict, or overlap with any existing Federal rules.

This final rule does not contain a collection of information requirement for the purposes of the Paperwork Reduction Act.

The Chief Counsel for Regulation for the Department of Commerce certified to the Small Business Administration that the 2019–2021 blueline tilefish specifications rulemaking would not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act. No comments were received that would change the initial certification. Because advance notice and the opportunity for public comment are not required for this action under the Administrative Procedure Act, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* do not apply to this rule. Therefore, no new regulatory flexibility analysis is required and none has been prepared.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: February 12, 2020.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2020–03198 Filed 2–14–20; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 85, No. 32
Tuesday, February 18, 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.

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

5 CFR Parts 1600 and 1650

Automatic Enrollment Program

AGENCY: Federal Retirement Thrift Investment Board.

ACTION: Proposed rule.

SUMMARY: The Federal Retirement Thrift Investment Board (FRTIB) is proposing to amend its regulations to increase the automatic enrollment percentage from 3 percent to 5 percent of basic pay for all participants who are automatically enrolled in the Thrift Savings Plan (TSP) on or after October 1, 2020 and for Blended Retirement Service (BRS) participants who are automatically re-enrolled in the TSP on or after January 1, 2021. In addition, the FRTIB is proposing a non-substantive clarification regarding installment payments calculated based on life expectancy.

DATES: Comments must be received on or before April 20, 2020.

ADDRESSES: You may submit comments using one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 942–1676.
- *Mail or Hand Deliver/Courier:* Office of General Counsel, Attn: Megan G. Grumbine, Federal Retirement Thrift Investment Board, 77 K Street NE, Suite 1000, Washington, DC 20002.

FOR FURTHER INFORMATION CONTACT: Austen Townsend, (202) 864–8647.

SUPPLEMENTARY INFORMATION: The FRTIB administers the Thrift Savings Plan (TSP), which was established by the Federal Employees' Retirement System Act of 1986 (FERSA), Public Law 99–335, 100 Stat. 514. The TSP provisions of FERSA are codified, as amended, largely at 5 U.S.C. 8351 and 8401–79. The TSP is a tax-deferred retirement savings plan for federal civilian employees and members of the uniformed services. The TSP is similar to cash or deferred arrangements established for private-sector employees under section 401(k) of the Internal Revenue Code (26 U.S.C. 401(k)).

Automatic Enrollment

The Thrift Savings Plan Enhancement Act of 2009 authorized the FRTIB to add an automatic enrollment program for all Federal employees eligible to participate in the TSP. The National Defense Authorization Act for Fiscal Year 2016 extended the automatic enrollment program, with an additional automatic re-enrollment feature, to certain members of the uniformed services. Under the automatic enrollment program, the Executive Director has the statutory authority to select a default contribution rate for automatically enrolled participants that is no less than 2 percent and no more than 5 percent of basic pay.

Currently, the following participants are automatically enrolled in the TSP at the statutory default rate of 3 percent: (1) Federal Employees Retirement System (FERS) participants hired or rehired after July 31, 2010; (2) Civil Service Retirement System (CSRS) participants rehired after July 31, 2010; (3) members of the uniformed services who began serving on or after January 1, 2018 (BRS participants); and (4) rehired BRS participants (whether automatically enrolled or opt-ins). In addition, BRS participants subject to automatic enrollment who terminate their TSP contributions at any point during the year and do not elect to resume them by the last full pay period of the year are automatically re-enrolled at a contribution rate of 3 percent as of January 1st of the following year.

The FRTIB proposes to increase the automatic enrollment rate and the automatic re-enrollment rate to 5 percent, effective October 1, 2020 and January 1, 2021, respectively. Participants who are automatically enrolled in the TSP as of September 30, 2020 will not be affected by the automatic enrollment rate increase. However, BRS participants who are automatically enrolled in the TSP as of September 30, 2020 and subsequently terminate their TSP contributions will be affected by the automatic re-enrollment rate increase unless they elect to resume TSP contributions by the last full pay period of the year. All participants may elect to change their contribution rates at any time by contacting their respective agencies.

The TSP's goal is to help federal employees and members of the uniformed services retire with dignity. As of December 31, 2018, 26 percent of TSP participants were contributing less than 5 percent to their accounts, which means they were not receiving the full amount of Agency/Service Matching Contributions they are entitled to.

Increasing the rate to 5 percent not only increases the amount that a participant saves from his or her basic pay, but also ensures that that participant receives the full amount of Agency/Service Matching Contributions he or she is entitled to, both of which will allow the participant, everything else being equal, to achieve significantly greater retirement savings.

Installment Payments Calculated Based on Life Expectancy

The FRTIB is proposing to amend its rule regarding installment payments calculated based on life expectancy to clarify that, for each year following the year in which the installment payments begin, the installment payment amount for the year will be calculated on the first installment payment date of that year.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities. This regulation will affect Federal employees, members of the uniformed services who participate in the TSP, and beneficiary participants.

Paperwork Reduction Act

I certify that these regulations do not require additional reporting under the criteria of the Paperwork Reduction Act.

Unfunded Mandates Reform Act of 1995

Pursuant to the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 602, 632, 653, and 1501–1571, the effects of this regulation on state, local, and tribal governments and the private sector have been assessed. This regulation will not compel the expenditure in any one year of $100 million or more by state, local, and tribal governments, in the aggregate, or by the private sector. Therefore, a statement under 2 U.S.C. 1532 is not required.

List of Subjects

5 CFR Part 1600

Government employees, Pensions, Retirement.

5 CFR Part 1650

Alimony, Claims, Government employees, Pensions, Retirement.

Ravindra Deo,

Executive Director, Federal Retirement Thrift Investment Board.

For the reasons stated in the preamble, the FRTIB proposes to amend 5 CFR Chapter VI as follows:

PART 1600—EMPLOYEE CONTRIBUTION ELECTIONS, CONTRIBUTION ALLOCATIONS, AND AUTOMATIC ENROLLMENT PROGRAM

■ 1. The authority citation will continue to read as follows:

Authority: 5 U.S.C. 8351, 8432(a), 8432(b), 8432(c), 8432(j), 8432d, 8474(b)(5) and (c)(1), and 8440e.

§ 1600.34 [Amended]

■ 2. In § 1600.34, amend paragraphs (a), (b), and (c) by removing the term ''3%'' and adding the term ''5%'' in its place.

§ 1600.37 [Amended]

■ 3. In § 1600.37, amend paragraph (a) by removing the term ''3 percent'' and adding the term ''5 percent'' in its place.

PART 1650—METHODS OF WITHDRAWING FUNDS FROM THE THRIFT SAVINGS PLAN

■ 4. The authority citation continues to read as follows:

Authority: 5 U.S.C. 8351, 8432d, 8433, 8434, 8435, 8474(b)(5) and 8474(c)(1).

■ 5. Amend § 1650.13 by revising paragraph (a)(2) to read as follows:

§ 1650.13 Installment payments.

(a) * * *

(2) *An installment payment amount calculated based on life expectancy.* Payments based on life expectancy are determined using the factors set forth in the Internal Revenue Service life expectancy tables codified at 26 CFR 1.401(a)(9)–9, Q&A 1 and 2. The installment payment amount is calculated by dividing the account balance by the factor from the IRS life expectancy tables based upon the participant's age as of his or her birthday in the year payments are to begin. This amount is then divided by the number of installment payments to be made per calendar year to yield the installment payment amount. In subsequent years, the installment payment amount is recalculated on the first installment payment date of the year by dividing the prior December 31 account balance by the factor in the IRS life expectancy tables based upon the participant's age as of his or her birthday in the year payments will be made. There is no minimum amount for an installment payment calculated based on this method.

* * * * *

[FR Doc. 2020–03102 Filed 2–14–20; 8:45 am]

BILLING CODE 6760–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0092; Product Identifier 2020–NM–001–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Bombardier, Inc., Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes, Model CL–600–2C10 (Regional Jet Series 700, 701 & 702) airplanes, Model CL–600–2D15 (Regional Jet Series 705) airplanes, and Model CL–600–2D24 (Regional Jet Series 900) airplanes; and all Model CL–600–2C11 (Regional Jet Series 550) airplanes. This proposed AD was prompted by reports of fractured rudder primary feel unit shafts; a subsequent investigation determined that the fractures in the shafts are consistent with fatigue damage. This proposed AD would require replacement of the rudder primary feel unit shaft. 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 April 3, 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 Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; Widebody Customer Response Center North America toll-free telephone 1–866–538–1247 or direct-dial telephone 1–514–855–2999; fax 514–855–7401; email *ac.yul@aero.bombardier.com;* internet *http://www.bombardier.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

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–2020–0092; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the 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: Andrea Jimenez, Aerospace Engineer, Airframe and Mechanical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7330; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2020–0092; Product Identifier 2020–NM–001–AD'' at the beginning of your comments. The FAA specifically invite 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 NPRM.

Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF–2019–42, dated November 8, 2019 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Bombardier, Inc., Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes, Model CL–600–2C10 (Regional Jet Series 700, 701 & 702) airplanes, Model CL–600–2D15 (Regional Jet Series 705) airplanes, and Model CL–600–2D24 (Regional Jet Series 900) airplanes; and all Model CL–600–2C11 (Regional Jet Series 550) airplanes. You may examine the MCAI in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0092.

This proposed AD was prompted by reports of fractured rudder primary feel unit shafts; a subsequent investigation determined that the fractures in the shafts are consistent with fatigue damage. The FAA is proposing this AD to address fractures of the rudder primary feel unit shaft, which could result in a loss of feel in the yaw axis and thereby impact the controllability of the airplane. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

Bombardier has issued Service Bulletin 601R–27–166, dated April 5, 2019, and Service Bulletin 670BA–27–075, dated April 5, 2019. This service information describes procedures for replacing the rudder primary feel unit shaft that has part number 600–90251–1 with a new shaft. These documents are distinct since they apply to different airplane models. 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

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, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed Requirements of This NPRM

This proposed AD would require accomplishing the actions specified in the service information described previously.

Costs of Compliance

The FAA estimates that this proposed AD affects 1,002 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
18 work-hours × $85 per hour = $1,530	$158	$1,688	$1,691,376

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 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 adding the following new airworthiness directive (AD):

Bombardier, Inc.: Docket No. FAA–2020–0092; Product Identifier 2020–NM–001–AD.

(a) Comments Due Date

We must receive comments by April 3, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc. airplanes, certificated in any category, as specified in paragraphs (c)(1) through (4) of this AD.

(1) Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes, serial number (S/N) 7003 through 7990 inclusive, and S/N 8000 and subsequent.

(2) Model CL–600–2C10 (Regional Jet Series 700, 701 & 702) airplanes, S/N 10002 through 10347 inclusive.

(3) Model CL–600–2D15 (Regional Jet Series 705) airplanes and Model CL–600–2D24 (Regional Jet Series 900) airplanes, S/N 15001 through 15469 inclusive.

(4) Model CL–600–2C11 (Regional Jet Series 550) airplanes, all serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls.

(e) Reason

This AD was prompted by reports of fractured rudder primary feel unit shafts; a subsequent investigation determined that the fractures in the shafts are consistent with fatigue damage. The FAA is issuing this AD to address fractures of the rudder primary feel unit shaft, which could result in a loss of feel in the yaw axis and thereby impact the controllability of the airplane.

(f) Compliance

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

(g) Replacement

Within the compliance times specified in figure (1) to paragraph (g) of this AD: Replace all rudder primary feel unit shafts that have part number (P/N) 600–90251–1 with a new shaft, in accordance with the Accomplishment Instructions of the Bombardier Service Bulletin 601R–27–166, dated April 5, 2019; or Bombardier Service Bulletin 670BA–27–075, dated April 5, 2019; as applicable. For Model CL–600–2C11 (Regional Jet Series 550) airplanes, do the replacement in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 670BA–27–075, dated April 5, 2019.

Figure 1 to paragraph (g) – *Compliance Times*

Accumulated Airplane Flight Cycles	Compliance Time for the Replacement
For airplanes that have accumulated 22,000 total flight cycles or less as of the effective date of this AD.	Before the airplane reaches 30,000 total flight cycles.
For airplanes that have accumulated more than 22,000 total flight cycles, but less than 37, 000 total flight cycles as of the effective date of this AD.	Within 8,000 flight cycles from the effective date of this AD.
For airplanes that have accumulated 37,000 total flight cycles or more, but less than 40,000 total flight cycles as of the effective date of this AD.	Before the airplane reaches 45,000 total flight cycles.
For airplanes that have accumulated 40,000 total flight cycles or more, but less than 46,500 total flight cycles as of the effective date of this AD.	Within 5,000 flight cycles from the effective date of this AD.
For airplanes that have accumulated 46,500 total flight cycles or more as of the effective date of this AD.	Before the airplane reaches 51,500 total flight cycles.

(h) Parts Installation Prohibition

As of the effective date of this AD, no person may install a rudder primary feel unit shaft, P/N 600–90251–1, on any airplane.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2019–42, dated November 8, 2019, for related information. This MCAI may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0092.

(2) For more information about this AD, contact Andrea Jimenez, Aerospace Engineer, Airframe and Mechanical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7330; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; Widebody Customer Response Center North America toll-free telephone 1–866–538–1247 or direct-dial telephone 1–514–855–2999; fax 514–855–7401; email *ac.yul@aero.bombardier.com*; internet *http://www.bombardier.com.* You may view this service information at the FAA, Transport Standards 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 February 11, 2020.

Gaetano A. Sciortino,

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

[FR Doc. 2020–03042 Filed 2–14–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–1115; Product Identifier 2018–SW–065–AD]

RIN 2120–AA64

Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Sikorsky Aircraft Corporation (Sikorsky) Model S–92A helicopters. This proposed AD was prompted by two incidents of erroneous low oil pressure caution cockpit indications and unintended actuation of the main gearbox (MGB) auto bypass valve. This proposed AD would require installing auxiliary circuit breaker modification (MOD) kits and inserting a Rotorcraft Flight Manual (RFM) Supplement into the RFM for your helicopter. 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 April 3, 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 your local Sikorsky Field Representative or Sikorsky's Service Engineering Group at Sikorsky Aircraft Corporation, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800–Winged–S; email *wcs_cust_service_eng.gr-sik@lmco.com.* Operators may also log on to the Sikorsky 360 website at *https://www.sikorsky360.com.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110.

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–2019–1115; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the 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: Michael Schwetz, Aviation Safety Engineer, Boston ACO Branch, Compliance & Airworthiness Division, FAA, 1200 District Avenue, Burlington, MA 01803; telephone 781–238–7761; email *michael.schwetz@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–2019–1115; Product Identifier 2018–SW–065–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 NPRM.

Discussion

The FAA proposes to adopt a new AD for Sikorsky Model S–92A helicopters. This proposed AD is prompted by two incidents of erroneous low oil pressure caution cockpit indications and unintended actuation of the MGB auto bypass valve caused by unintended popping of the M XMSN OIL WARN circuit breaker during flight. The root cause of this circuit breaker popping is unknown. When this circuit breaker trips, the following cautions will display ''MGB PUMP 1 FAIL, MGB PUMP 2 FAIL, MGB OIL HOT, MGB MAN COOL, MGB OIL PRES.'' With the MGB auto bypass valve actuated, the MGB BYPASS caution will not annunciate. For the given conditions, the appropriate action for the crew is ''land as soon as possible'' in accordance with the RFM Emergency Procedures. The erroneous indications conflicting with correct gauge readings may overwhelm the flight crew, resulting in a forced landing of the helicopter.

To address this unsafe condition, Sikorsky developed MOD kits based on helicopter serial number (S/N) to introduce a separate circuit breaker for the MGB last jet pressure switch. These MOD kits specify reworking the overhead panel to install new clips and brackets, circuit breaker wiring harnesses, wiring MODs, the auxiliary circuit breaker panel, and the M XMSN PRESS SWITCH circuit breaker.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Sikorsky Special Service Instructions No. 92–121, dated October 26, 2017 (SSI 92–121). This service information describes procedures for installing an auxiliary circuit breaker panel MOD kit and M XMSN PRESS SWITCH circuit breaker MOD kit based on helicopter S/N.

The FAA also reviewed RFM Supplement No. 45, Revision No. 2, Sikorsky Model S–92A, Part 1, dated April 27, 2017 (S–92A RFMS 45, Part 1, Revision 2). This service information specifies operating limitations, preflight checks, normal and emergency procedures, and malfunction information for helicopters with Avionics Management System version 7.1 or 8.0 with the MGB OIL OUT warning activated, pump failure indicating system, MGB auto bypass, and M XMSN PRESS SWITCH circuit breaker installed.

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.

Other Related Service Information

The FAA reviewed Sikorsky S–92 Helicopter Alert Service Bulletin 92–63–037, Revision A, dated March 1, 2018. This service information contains planning information pertaining to the auxiliary circuit breaker panel and M XMSN PRESS SWITCH circuit breaker MOD kits, accomplishing SSI 92–121, and inserting S–92A RFMS 45, Part 1, Revision 2 into the helicopter cockpit.

FAA's Determination

The FAA is proposing this AD after evaluating all the relevant information and determining that 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 require, within 400 hours time-in-service:

- For helicopters S/N 920006 through 920296 inclusive, installing an auxiliary circuit breaker panel and M XMSN PRESS SWITCH circuit breaker by installing MOD Kit Clips and Brackets part number (P/N) 92070–20115–015, MOD Kit Left Hand (LH) Cockpit Auxiliary Power Unit P/N 92070–55096–012, MOD Kit LH Cabin Auxiliary Power Unit P/N 92070–55096–013, MOD Kit LH Top Deck FLD P/N 92070–55096–016, MOD Kit MGB XMSN P/N 92070–55096–017, MOD Kit Auxiliary Circuit Break Panel P/N 92070–55075–011, and MOD Kit Auxiliary Cabin Panel Faceplate P/N 92070–55075–012.
- For helicopters S/N 920297 through 920304 inclusive and S/N 920311 through 920314 inclusive, modifying the auxiliary circuit breaker panel and transmission harness and installing MOD Kit Auxiliary Cabin Panel Faceplate P/N 92070–55075–012.
- Inserting a copy of S–92A RFMS 45, Part 1, Revision 2 into the RFM for your helicopter.

Costs of Compliance

The FAA estimates that this proposed AD affects 36 helicopters of U.S. registry. The FAA estimate the following costs to comply with this proposed AD. Labor costs are estimated at $85 per work-hour.

Modifying helicopters S/N 920006 through 920296 inclusive would take about 48 work-hours and parts would cost about $1,618 for an estimated cost of $5,698 per helicopter and $182,336 for the U.S. fleet size of 32 helicopters.

Modifying helicopters S/N 920297 through 920304 inclusive and S/N 920311 through 920314 inclusive would take about 2 work-hours and parts would cost about $65 for an estimated cost of $235 per helicopter and $940 for the U.S. fleet size of 4 helicopters.

Revising the RFM would take about 0.5 work-hour for an estimated cost of $43 per helicopter and $1,548 for the U.S. fleet.

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA 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.

The FAA prepared an economic evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Sikorsky Aircraft Corporation: Docket No. FAA–2019–1115; Product Identifier 2018–SW–065–AD.

(a) Comments Due Date

The FAA must receive comments by April 3, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Sikorsky Aircraft Corporation Model S–92A helicopters, serial number (S/N) 920006 through 920304 inclusive and S/N 920311 through 920314 inclusive, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code: 6340, Rotor Drive Indicating System.

(e) Unsafe Condition

This AD was prompted by two incidents of erroneous low oil pressure caution cockpit indications and unintended actuation of the main gearbox (MGB) auto bypass valve. The FAA is issuing this AD to prevent the M XMSM OIL WARN circuit breaker from presenting erroneous cautions when tripped. The unsafe condition, if not addressed, could result in erroneous low oil pressure caution cockpit indication, unintended actuation of the MGB auto bypass valve, increased oil temperature, conflicting indications, and forced landing of the helicopter.

(f) Compliance

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

(g) Required Actions

Within 400 hours time-in-service:

(1) For helicopters S/N 920006 through 920296 inclusive:

(i) Install Modification (MOD) Kit Clips and Brackets part number (P/N) 92070–20115–015 by following the Instructions, paragraph B. of Sikorsky Special Service Instructions No. 92–121, dated October 26, 2017 (SSI 92–121).

(ii) Install the first portion of MOD Kit Auxiliary Circuit Breaker Panel P/N 92070–55075–011 by following the Instructions, paragraph C. of Sikorsky SSI 92–121.

(iii) Install MOD Kit Left Hand (LH) Cockpit Auxiliary Power Unit P/N 92070–55096–012 by following the Instructions, paragraph D. of Sikorsky SSI 92–121.

(iv) Install MOD Kit LH Cabin Auxiliary Power Unit P/N 92070–55096–013 by following the Instructions, paragraph E. of Sikorsky SSI 92–121.

(v) Install MOD Kit LH Top Deck FLD P/N 92070–55096–016 by following the Instructions, paragraph F. of Sikorsky SSI 92–121.

(vi) Install MOD Kit MGB XMSN P/N 92070–55096–017 by following the Instructions, paragraph G. of Sikorsky SSI 92–121.

(vii) Install the completion portion of MOD Kit Auxiliary Circuit Break Panel P/N 92070–55075–011 by following the Instructions, paragraph H. of Sikorsky SSI 92–121.

(viii) Install MOD Kit Auxiliary Cabin Panel Faceplate P/N 92070–55075–012 by following the Instructions, paragraph J. of Sikorsky SSI 92–121.

(2) For helicopters S/N 920297 through 920304 inclusive and S/N 920311 through 920314 inclusive:

(i) Modify the auxiliary circuit breaker panel and transmission harness by following the Instructions, paragraph I. of Sikorsky SSI 92–121.

(ii) Install MOD Kit Auxiliary Cabin Panel Faceplate P/N 92070–55075–012 by following the Instructions, paragraph J. of Sikorsky SSI 92–121.

(3) Insert a copy of the Rotorcraft Flight Manual (RFM) Supplement No. 45, Revision No. 2, Sikorsky Model S–92A, Part 1, dated April 27, 2017, into the RFM for your helicopter.

(h) Credit for Previous Actions

Completion of the Accomplishment Instructions of Sikorsky S–92 Helicopter Alert Service Bulletin 92–63–037, Revision A, dated March 1, 2018, before the effective date of this AD is considered acceptable for compliance with the actions required by paragraph (g) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD.

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

(j) Related Information

(1) For more information about this AD, contact Michael Schwetz, Aviation Safety Engineer, Boston ACO Branch, Compliance & Airworthiness Division, FAA, 1200 District Avenue, Burlington, MA 01803; telephone 781–238–7761; email *michael.schwetz@faa.gov.*

(2) For service information identified in this AD, contact your local Sikorsky Field Representative or Sikorsky's Service Engineering Group at Sikorsky Aircraft Corporation, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800–Winged–S; email *wcs_cust_service_eng.gr-sik@lmco.com.* Operators may also log on to the Sikorsky 360 website at *https://www.sikorsky360.com.* You may view this referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110.

Issued in Fort Worth, Texas, on February 4, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–03072 Filed 2–14–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0094; Product Identifier 2019–NM–188–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) 2018–06–07, which applies to all The Boeing Company Model 757–200, –200CB, and –300 series airplanes. AD 2018–06–07 requires inspecting the fuselage frame at a certain station for existing repairs, repetitive inspections, and applicable repairs. Since the FAA issued AD 2018–06–07, the agency has received reports of new crack findings outside of the AD 2018–06–07 inspection area, which the current inspections will not detect. This proposed AD would continue to require the actions in AD 2018–06–07, with an expanded inspection area, additional inspections, a modified inspection type, and applicable repairs. 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 April 3, 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 Boeing 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; phone: 562–797–1717; internet: *https://www.myboeingfleet.com.*

For Aviation Partners Boeing service information identified in this NPRM, contact Aviation Partners Boeing, 2811 S 102nd Street, Suite 200, Seattle, WA 98168; phone: 206–830–7699; internet: *https://www.aviationpartnersboeing.com.*

You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. Boeing Alert Service Bulletin 757–53A0108, Revision 1, dated July 17, 2019, is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0094.

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–2020–0094; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the 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: Peter Jarzomb, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5234; fax: 562–627–5210; email: *peter.jarzomb@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–2020–0094; Product Identifier 2019–NM–188–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 2018–06–07, Amendment 39–19227 (83 FR 13398, March 29, 2018) (''AD 2018–06–07''), for all The Boeing Company Model 757–200, –200CB, and –300 series airplanes. AD 2018–06–07 requires inspecting the fuselage frame at station (STA) 1640 for existing repairs, repetitive inspections, and applicable repairs. AD 2018–06–07 resulted from a report of fatigue cracking found in a certain fuselage frame, which severed the inner chord and web. The FAA issued AD 2018–06–07 to address cracking of the fuselage frame at STA 1640, which could result in reduced structural integrity of the airplane.

Actions Since AD 2018–06–07 Was Issued

Since the FAA issued AD 2018–06–07, the FAA has received reports of new crack findings outside of the AD 2018–06–07 inspection area. During the inspections required by AD 2018–06–07, an operator found the STA 1640 frame with a crack starting from the third fastener below the stringer S–14 intercostal on the right side. The crack was approximately 3 inches long and had grown into an insulation stud hole in the web near the outer chord. The crack was not in the area inspected as required by AD 2018–06–07. There have also been reports of cracks found growing out of the fastener holes in the inner chord in the aft direction, towards the web away from the original inspection areas. The FAA has therefore determined that the inspection area must be expanded and new inspections must be added.

Related Service Information Under 1 CFR Part 51

The FAA has reviewed Boeing Alert Service Bulletin 757–53A0108, Revision 1, dated July 17, 2019. This service information describes procedures for an inspection of the fuselage frame for existing frame repairs or replacements, a detailed inspection for any crack, nick, or gouge in the STA 1640 fuselage frame, repetitive high frequency eddy current and low frequency eddy current inspections for cracking in the STA 1640 fuselage frame between stringers S–11 and S–16, and repair.

The FAA has also reviewed Aviation Partners Boeing (APB) Alert Service Bulletin AP757–53–001, Revision 2, dated October 22, 2019. This service information provides compliance times for accomplishing the procedures identified in Boeing Alert Service Bulletin 757–53A0108, Revision 1, dated July 17, 2019, for airplanes on which APB blended or scimitar blended winglets are installed.

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 FAA has 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

Although this proposed AD does not explicitly restate the requirements of AD 2018–06–07, this proposed AD would retain certain requirements of AD 2018–06–07. Those requirements are referenced in the service information identified previously, which, in turn, is referenced in paragraph (g) of this proposed AD. This proposed AD would expand the inspection area, add inspections, and modify a certain inspection type.

This proposed AD would also require accomplishment of the actions identified as ''RC'' (required for compliance) in the Accomplishment Instructions of Boeing Alert Service Bulletin 757–53A0108, Revision 1, dated July 17, 2019; and Aviation Partners Boeing (APB) Alert Service Bulletin AP757–53–001, Revision 2, dated October 22, 2019, described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

The initial compliance times for the airplanes identified in Boeing Alert Service Bulletin 757–53A0108, Revision 1, dated July 17, 2019, range from within 500 flight cycles after the effective date of this AD, to within 16,000 flight cycles after the installation of the local frame replacement, depending on the configuration. The repetitive intervals range from 1,800 flight cycles to 10,400 flight cycles, depending on the configuration.

The initial compliance times for the airplanes identified in Aviation Partners Boeing (APB) Alert Service Bulletin AP757–53–001, Revision 2, dated October 22, 2019, range from within 500 flight cycles after the effective date of this AD, to within 16,000 flight cycles after the installation of the local frame replacement, depending on the configuration. The repetitive intervals range from 1,900 flight cycles to 8,600 flight cycles, depending on the configuration.

For information on the procedures and compliance times, see Boeing Alert Service Bulletin 757–53A0108, Revision 1, dated July 17, 2019, at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0094.

Costs of Compliance

The FAA estimates that this proposed AD affects 606 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection for existing frame repairs or replacements.	1 work-hour × $85 per hour = $85	$0	$85	$51,510.
Detailed inspection	1 work-hour × $85 per hour	0	$85	$51,510.

ESTIMATED COSTS FOR REQUIRED ACTIONS—Continued

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Repetitive high and low frequency inspections for Groups 1 through 3 airplanes (598 airplanes).	54 work-hours × $85 per hour = $4,590 per inspection cycle.	0	$4,590 per inspection cycle.	$2,744,820 per inspection cycle.
Repetitive high and low frequency inspections for Groups 4 and 5 airplanes (8 airplanes).	49 work-hours × $85 per hour = $4,165 per inspection cycle.	0	$4,165 per inspection cycle.	$33,320 per inspection cycle.

The FAA has received no definitive data that would enable us to provide cost estimates for the on-condition repair specified in this proposed AD.

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) 2018–06–07, Amendment 39–19227 (83 FR 13398, March 29, 2018), and adding the following new AD:

The Boeing Company: Docket No. FAA–2020–0094; Product Identifier 2019–NM–188–AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by April 3, 2020.

(b) Affected ADs

This AD replaces AD 2018–06–07, Amendment 39–19227 (83 FR 13398, March 29, 2018) (''AD 2018–06–07'').

(c) Applicability

This AD applies to all The Boeing Company Model 757–200, –200CB, and –300 series airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by a report of fatigue cracking found in the fuselage frame at station (STA) 1640, which severed the inner chord and web. The FAA is issuing this AD to address cracking of the fuselage frame at STA 1640, which could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Actions Required for Compliance

(1) For all airplanes except those identified in paragraphs (g)(2) through (4) of this AD: Except as specified by paragraph (h) of this AD, at the applicable times specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 757–53A0108, Revision 1, dated July 17, 2019, do all applicable actions identified as ''RC'' (required for compliance) in, and in accordance with, the Accomplishment Instructions of Boeing Alert Service Bulletin 757–53A0108, Revision 1, dated July 17, 2019.

(2) For airplanes on which Aviation Partners Boeing (APB) blended or scimitar blended winglets are installed using Supplemental Type Certificate (STC) ST01518SE: Except as specified by paragraph (h) of this AD, at the applicable times specified in paragraph 1.E., ''Compliance,'' of Aviation Partners Boeing (APB) Alert Service Bulletin AP757–53–001, Revision 2, dated October 22, 2019, do all applicable actions identified as ''RC'' in, and in accordance with, the Accomplishment Instructions of Aviation Partners Boeing (APB) Alert Service Bulletin AP757–53–001, Revision 2, dated October 22, 2019.

(3) For Group 1 airplanes that have been converted from passenger to freighter configuration using VT Mobile Aerospace Engineering (MAE) Inc. STC ST03562AT: Except as specified by paragraph (h) of this AD, at the applicable times specified for Group 2 airplanes in the ''Compliance'' paragraph of Boeing Alert Service Bulletin 757–53A0108, Revision 1, dated July 17, 2019, do all applicable Group 2 actions, as identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Service Bulletin 757–53A0108, Revision 1, dated July 17, 2019.

(4) For Group 4 airplanes that have been converted from a passenger to freighter configuration using VT MAE Inc. STC ST03562AT: Except as specified by paragraph (h) of this AD, at the applicable times specified for Group 5 airplanes in the ''Compliance'' paragraph of Boeing Alert Service Bulletin 757–53A0108, Revision 1, dated July 17, 2019, do all applicable Group 5 actions as identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Service Bulletin 757–53A0108, Revision 1, dated July 17, 2019.

(h) Exceptions to Service Information Specifications

(1) Where Boeing Alert Service Bulletin 757–53A0108, Revision 1, dated July 17, 2019, specifies contacting Boeing for repair instructions or for alternative inspections: This AD requires doing the repair, or doing the alternative inspections and applicable on-condition actions using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(2) Where Boeing Alert Service Bulletin 757–53A0108, Revision 1, dated July 17, 2019, uses the phrase ''the original issue date of this service bulletin,'' this AD requires using ''May 3, 2018 (the effective date of AD 2018–06–07),'' except where Alert Service Bulletin 757–53A0108, Revision 1, dated July 17, 2019, uses the phrase ''the original issue date of this service bulletin'' in a note or flag note.

(3) Where Boeing Alert Service Bulletin 757–53A0108, Revision 1, dated July 17, 2019, uses the phrase ''the revision 1 date of this service bulletin,'' this AD requires using ''the effective date of this AD.''

(4) Where Aviation Partners Boeing (APB) Alert Service Bulletin AP757–53–001, Revision 2, dated October 22, 2019, specifies contacting Boeing for repair instructions or for alternative inspections: This AD requires doing the repair, or doing the alternative inspections and applicable on-condition actions using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(5) Where Aviation Partners Boeing (APB) Alert Service Bulletin AP757–53–001, Revision 2, dated October 22, 2019, uses the phrase ''the revision 1 issue date of this service bulletin,'' this AD requires using ''May 3, 2018 (the effective date of AD 2018–06–07),'' except where Aviation Partners Boeing (APB) Alert Service Bulletin AP757–53–001, Revision 2, dated October 22, 2019, uses the phrase ''the revision 1 issue date of this service bulletin'' in a note or flag note.

(6) Where Aviation Partners Boeing (APB) Alert Service Bulletin AP757–53–001, Revision 2, dated October 22, 2019, uses the phrase ''the revision 2 issue date of this service bulletin,'' this AD requires using ''the effective date of this AD.''

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-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, Los Angeles 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 2018–06–07 are not approved as AMOCs for the corresponding provisions of this AD.

(5) Except as specified by paragraph (h) of this AD: For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (i)(5)(i) and (ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled ''RC Exempt,'' then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(j) Related Information

(1) For more information about this AD, contact Peter Jarzomb, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5234; fax: 562–627–5210; email: *peter.jarzomb@faa.gov.*

(2) For Aviation Partners Boeing service information identified in this AD, contact Aviation Partners Boeing, 2811 S 102nd Street, Suite 200, Seattle, WA 98168; phone: 206–830–7699; internet: *https://www.aviationpartnersboeing.com.*

(3) For Boeing 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; phone: 562–797–1717; internet: *https://www.myboeingfleet.com.*

(4) You may view this referenced service information at the FAA, Transport Standards 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 February 11, 2020.

Gaetano A. Sciortino,

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

[FR Doc. 2020–03084 Filed 2–14–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0097; Product Identifier 2019–NM–208–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 adopt a new airworthiness directive (AD) for all The Boeing Company Model 737–300, –400, and –500 series airplanes. This proposed AD was prompted by a report that a crack indication consistent with fatigue cracking was found on the left nacelle support overwing fitting flange fastener hole during teardown of a Model 737–300 series airplane. This proposed AD would require a general visual inspection of the strut to wing diagonal brace at a certain location for cracking. For certain airplanes, this proposed AD would also require an ultrasonic inspection of certain fasteners of the nacelle support overwing fitting at a certain location for cracking. For certain other airplanes, this proposed AD would also require a magnetic check of the nacelle support overwing fitting at a certain location to determine the material composition. This proposed AD would also require applicable on-condition actions. 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 April 3, 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 referenced service information at the FAA, Transport Standards 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–2020–0097.

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–2020–0097; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the 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: Wayne Ha, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5238; fax: 562–627–5210; email: *wayne.ha@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–2020–0097; Product Identifier 2019–NM–208–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, 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 agency receives about this proposed AD.

Discussion

The FAA has received a report indicating that a crack indication consistent with fatigue cracking was found on the left nacelle support overwing fitting flange fastener hole during teardown of a Model 737–300 series airplane. Further analysis determined the root cause of the crack is stress at the first two forward fasteners of the nacelle support overwing fitting being higher than anticipated. Existing maintenance planning document (MPD) inspections do not provide opportunities to detect a failed nacelle support overwing fitting at wing buttock line (WBL) 191. The crack finding occurred at 67,695 total flight cycles and 80,269 total flight hours. This condition, if not addressed, could result in an undetected crack in the nacelle support overwing fittings or strut to wing diagonal brace, which could result in the inability of the structure to carry limit load and could adversely affect the structural integrity of the airplane.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 737–57A1345 RB, dated December 17, 2019. This service information describes procedures for a magnetic check to determine material composition of the nacelle support overwing fitting at WBL 191; ultrasonic inspections of the nacelle support overwing fitting at WBL 191 for cracking; general visual inspections of the strut to wing diagonal brace at nacelle station (STA) 278 for cracking; and applicable on-condition actions. On-condition actions include repetitive ultrasonic inspections of the nacelle support overwing fitting at WBL 191 for cracking, repetitive general visual inspections of the strut to wing diagonal brace at nacelle STA 278 for cracking, and repair. 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 FAA 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 require accomplishment of the actions identified in Boeing Alert Requirements Bulletin 737–57A1345 RB, dated December 17, 2019, 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–2020–0097.

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 158 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Magnetic Check	1 work-hour × $85 per hour = $85	$0	$85	$13,430
Ultrasonic Inspection	5 work-hours × $85 per hour = $425	0	425	67,150
General Visual Inspection	1 work-hour × $85 per hour = $85	0	85	13,430

The FAA estimates the following costs to do any necessary on-condition inspections that would be required. The FAA has no way of determining the number of aircraft that might need these on-condition inspections:

ESTIMATED COSTS OF ON-CONDITION INSPECTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Ultrasonic Inspections	5 work-hours × $85 per hour = $425 per inspection cycle.	$0	$425 per inspection cycle	$67,150 per inspection cycle.
General Visual Inspections	1 work-hour × $85 per hour = $85 per inspection cycle.	0	$85 per inspection cycle	$13,430 per inspection cycle.

The FAA has received no definitive data that would enable us to provide cost estimates for the on-condition repairs specified in this proposed AD.

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 adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. FAA–2020–0097; Product Identifier 2019–NM–208–AD.

(a) Comments Due Date

The FAA must receive comments by April 3, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 737–300, –400, and –500 series airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Unsafe Condition

This AD was prompted by a report that a crack indication consistent with fatigue cracking was found on the left nacelle support overwing fitting flange fastener hole during teardown of a Model 737–300 series airplane. The FAA is issuing this AD to address the potential for undetected cracks in the nacelle support overwing fittings or strut to wing diagonal brace, which could result in the inability of the structure to carry limit load and could adversely affect the structural integrity of the airplane.

(f) Compliance

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

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 737–57A1345 RB, dated December 17, 2019, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 737–57A1345 RB, dated December 17, 2019. Actions identified as terminating actions in Boeing Alert Requirements Bulletin 737–57A1345 RB, dated December 17, 2019, terminate the applicable required actions of this AD, provided the terminating action is done in accordance with the Accomplishment Instructions of Boeing Alert Requirements Bulletin 737–57A1345 RB, dated December 17, 2019.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 737–57A1345, dated December 17, 2019, which is referred to in Boeing Alert Requirements Bulletin 737–57A1345 RB, dated December 17, 2019.

(h) Exceptions to Service Information Specifications

(1) Where Boeing Alert Requirements Bulletin 737–57A1345 RB, dated December 17, 2019, uses the phrase ''the original issue date of Requirements Bulletin (RB) 737–57A1345 RB,'' this AD requires using ''the effective date of this AD.''

(2) Where Boeing Alert Requirements Bulletin 737–57A1345 RB, dated December 17, 2019, specifies contacting Boeing for repair instructions: This AD requires doing the repair before further flight using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-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, Los Angeles 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.

(j) Related Information

(1) For more information about this AD, contact Wayne Ha, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5238; fax: 562–627–5210; email: *wayne.ha@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, Transport Standards 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 February 11, 2020.

Gaetano A. Sciortino,

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

[FR Doc. 2020–03083 Filed 2–14–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2019–1022; Airspace Docket No. 19–ANM–81]

RIN 2120–AA66

Proposed Amendment of Class E Airspace and Establishment of Class E Airspace Extension; Port Angeles, WA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify the Class E surface area, Class E airspace extending upward from 700 feet above the surface and create Class E airspace as an extension to the Class E surface area at William R Fairchild International Airport, Port Angeles, WA. Following a review of the airspace, the FAA found it necessary to modify the existing airspace for William R Fairchild Airport for the safety and management of Instrument Flight Rules (IFR) operations at the Airport.

DATES: Comments must be received on or before April 3, 2020.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: (800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2019–1022; Airspace Docket No. 19–ANM–81, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

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

FOR FURTHER INFORMATION CONTACT: Richard Roberts, Federal Aviation Administration, Operations Support Group, Western Service Center, 2200 S 216th Street, Des Moines, WA 98198–6547; telephone (206) 231–2245.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the existing Class E airspace and establish new Class E airspace as an extension to the Class E surface area at William R Fairchild International Airport, Port Angeles, WA, in support of IFR operations at the airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2019–1022; Airspace Docket No. 19–ANM–81) and be submitted in triplicate to DOT Docket Operations (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2019–1022; Airspace Docket No. 19–ANM–81.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

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

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays, at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S 216th St., Des Moines, WA 98198–6547.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order

7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by amending the Class E airspace description for William R Fairchild International Airport, Port Angeles, WA. This action is being submitted coincidental with an FAA proposal, Docket No. FAA–2019–1023; 19–ANM–94 to establish Class E airspace for Port Angeles CGAS, Port Angeles, WA. That action would provide the airspace needed for independent operations at Port Angeles CGAS to facilitate training and mission accomplishment. This action would modify the airspace at William R Fairchild International Airport, Port Angeles, WA, to only that airspace needed for their operations. The Class E surface area would be modified to include the airspace within 4.1 miles of the airport from the 235° bearing clockwise to the 120° bearing and exclude the airspace within 1.5 miles of the Port Angeles CGAS. This exclusion would allow independent air traffic operations at the Port Angeles CGAS when weather conditions at this location varies from those at the William R Fairchild International Airport.

A Class E extension to the surface area would be established 2 miles both sides of the 284° bearing extending from the 4.1-mile radius to 8 miles west of the airport. This would provide the airspace required for the RNAV approach to runway 8, as aircraft descend through 1000 feet AGL.

The Class E airspace extending upward from 700 feet AGL would be modified to within 4.1 miles of William R Fairchild International Airport and that area 3.1 miles on both sides of the 284° bearing from the airport to 11 miles west. This area would provide airspace for the RNAV and the ILS Approach to runway 8, as aircraft descend through 1500 feet.

To the southeast, the airspace extending upward from 700 feet AGL would be modified to 1-mile north and 4 miles south of the 105° bearing from the 4.1-mile radius to 7 miles from the airport.

This action would also remove the Class E surface airspace 3 miles north and 2.2 miles south of the William R Fairchild international Airport 079° bearing extending from the 4.1-mile radius to 11.4 miles east of the airport, as it is not needed for operations at William R. Fairchild airport. This airspace would support IFR operations at William R Fairchild Airport, Port Angeles, WA.

Class E airspace designations are published in paragraph 6002, 6004 and 6005 of FAA Order 7400.11D, dated August 8, 2019 and effective September 15, 2019, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order. FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019, is amended as follows:

Paragraph 6002 Class E Airspace Designated as Surface Areas.

* * * * *

ANM WA E2 Port Angeles, WA [Amended]

William R. Fairchild International Airport, WA
(Lat. 48°07′13″ N, long. 123°29′59″ W)
Port Angeles CGAS
(Lat. 48°08′29″ N, long. 123°24′50″ W)

That airspace within a 4.1-mile radius of the William R. Fairchild International Airport from the 235° bearing clockwise to the 120° bearing excluding the airspace within 1.5 miles of the Port Angeles CGAS.

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

ANM WA E4 Port Angeles, WA [New]

William R. Fairchild International Airport, WA
(Lat. 48°07′13″ N, long. 123°29′59″ W)

That airspace extending upward from the surface within 2 miles both sides of the 284° bearing extending from the 4.1 mile radius to 8 miles west of the airport.

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

* * * * *

ANM WA E5 Port Angeles, WA [Amended]

William R. Fairchild International Airport, WA
(Lat. 48°07′13″ N, long. 123°29′59″ W)

That airspace extending upward from 700 feet above the surface within a 4.1-mile radius of the William R. Fairchild International Airport, and within 1 mile north and 4 miles south of the William R. Fairchild International Airport 105° bearing extending from the 4.1-mile radius to 7 miles east of the airport and that airspace 3.1 miles each side of the 284° bearing from the 4.1-mile radius to 11 miles west of the airport.

Issued in Seattle, Washington, on February 11, 2020.

Stephanie C. Harris,

Group Manager (Acting), Operations Support Group, Western Service Center.

[FR Doc. 2020–03074 Filed 2–14–20; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Part 303

RIN 3084–AB28

Rules and Regulations Under the Textile Fiber Products Identification Act

AGENCY: Federal Trade Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') proposes amending the Rules and Regulations under the Textile Fiber Products Identification Act (''Textile Rules'' or ''Rules'') to incorporate the most recent ISO 2076 standard for generic fiber names. The proposed amendment should reduce compliance costs and increase flexibility for firms providing textile fiber information to consumers.

DATES: Written comments must be received on or before March 19, 2020.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comments part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Textile Rules, 16 CFR part 303, Project No. P948404'' on your comment, and file your comment online through *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, write ''Textile Rules, 16 CFR part 303, Project No. P948404'' on your comment and on the envelope and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex C), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex C), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Jock Chung (202–326–2984), Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Textile Fiber Products Identification Act (''Textile Act'') [1] and Rules require marketers to, among other things, attach a label to each covered textile product disclosing: (1) The generic names and percentages by weight of the constituent fibers in the product; (2) the name under which the manufacturer or other responsible company does business or, in lieu thereof, the company's registered identification number; and (3) the name of the country where the product was processed or manufactured.[2]

Section 303.7 of the Textile Rules (generic names and definitions for manufactured fibers) establishes the generic names for manufactured fibers that must be used in the required fiber content disclosures by: (1) Listing the generic names and definitions the Commission has established through its textile petition process,[3] and (2) incorporating by reference the generic names and definitions set forth in the ISO 2076 standard.

The Commission incorporated the ISO 2076:1989 standard into § 303.7 in 1998 so that a ''manufacturer or other marketer of a fiber not listed in [16 CFR 303.7] but recognized in ISO's 1989 standard need not petition the Commission for recognition of the fiber name, but may simply use the ISO established name.'' [4] The Commission stated that it ''may accommodate future changes in the ISO Standard by amending the Textile Rules to incorporate the new Standard without going through the petition process.'' [5] It also recommended that ''. . . manufacturers seeking recognition of new fiber names first seek recognition from the ISO,'' [6] noting that ''FTC recognition of new fibers by ISO in the future . . . can be accomplished easily by amending the Textile Rules to incorporate the most recent ISO standard.'' [7] The Commission subsequently incorporated the updated 2076:1999(E) standard into § 303.7 in 2000,[8] and incorporated the updated 2076:2010(E) standard in 2014.[9]

During these proceedings, commenters strongly supported incorporating the latest ISO 2076 standard in the Rule by asserting that doing so would expedite the use of new fiber names,[10] benefit businesses by establishing an international consensus that removes unnecessary barriers to trade, and help manufacturers develop labeling that satisfies the requirements of multiple countries.[11] Commenters further stated that incorporating updated ISO standards in the Rule reduces potential Customs challenges and helps forestall nationally biased standards that can create barriers to trade and hinder efficient supply-chain management.[12]

II. Proposed Amendment

The Commission proposes to incorporate the most recent version of the relevant standard, ISO 2076:2013(E), ''Textiles—Man-made fibres—Generic names,'' Sixth edition, November 15, 2013 (ISO 2076:2013(E)), in § 303.7 of the Textile Rule. The updated 2013 standard adds seven generic fiber names not defined in the 2010 standard: ''Chitin,'' ''ceramic,'' ''polybenzimidazol,'' ''polycarbamide,'' ''polypropylene/polyamide bicomponent,'' ''protein,'' and ''trivinyl.''

Commission staff has received several inquiries from manufacturers interested in initiating a proceeding to amend the Commission's list of approved generic fiber names under 16 CFR 303.8 to add ''chitin,'' a name recognized in ISO 2076:2013(E). Therefore, incorporating that standard into the Textile Rules will resolve the current requests, save the Commission and the manufacturers resources, and harmonize the two standards without the need to address other ISO recognized names individually.

III. Request for Comments

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before March 19, 2020. Write ''Textile Rules, 16 CFR part 303, Project No. P948404'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it through

[1] 15 U.S.C. 70 *et seq.*

[2] *See* 15 U.S.C. 70b(b).

[3] To establish a generic name under 16 CFR 303.8, the petitioner must submit evidence that: (1) The fiber has a chemical composition radically different from other fibers, and that the distinctive chemical composition results in distinctive physical properties of significance to the general public; (2) the fiber is in active commercial use or such use is immediately foreseen; and (3) the grant of the generic name is of importance to the consuming public at large. 38 FR 34112, 34114 (Dec. 11, 1973). The Commission must then review the evidence, solicit public comment on a proposed amendment to the Rules to add the generic name, and issue a final amendment to the Rules.

[4] 63 FR 7508, 7510 (Feb. 13, 1998).

[5] *Id.,* fn. 25.

[6] *Id.* at 7511.

[7] *Id.*

[8] 65 FR 75154 (Dec. 1, 2000).

[9] 79 FR 18766 (Apr. 4, 2014).

[10] 63 FR 7508, 7510.

[11] 78 FR 29263, 29265 (May 20, 2013).

[12] *Id.*

https://www.regulations.gov, by following the instruction on the web-based form provided.

If you file your comment on paper, write ''Textile Rules, 16 CFR part 303, Project No. P948404'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex C), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex C), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website, *https://www.regulations.gov,* you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure 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.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at *https://www.regulations.gov*—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website to read this NPRM and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before March 19, 2020. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

The Commission invites members of the public to comment on the costs and benefits to industry members and consumers, as well as any issues or concerns they believe are relevant or appropriate to the Commission's consideration of the proposed amendment to the Textile Rules. The Commission requests that comments provide factual data upon which they are based.

IV. Communications to Commissioners and Commissioner Advisors by Outside Parties

Written communications and summaries or transcripts of oral communications respecting the merits of this proceeding from any outside party to any Commissioner or Commissioner's advisor will be placed on the public record.[13]

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA'')[14] requires that the Commission conduct an analysis of the anticipated economic impact of the proposed amendment on small entities. The purpose of a regulatory flexibility analysis is to ensure that an agency considers potential impacts on small entities and examines regulatory alternatives that could achieve the regulatory purpose while minimizing burdens on small entities. The RFA requires that the Commission provide an Initial Regulatory Flexibility Analysis (''IRFA'') with a proposed rule and a Final Regulatory Flexibility Analysis (''FRFA'') with a final rule, if any, unless the Commission certifies that the rule will not have a significant economic impact on a substantial number of small entities.[15]

The Commission believes that the proposed amendment would not have a significant economic impact upon small entities, although it may affect a substantial number of small businesses. In the Commission's view, the proposed amendment should not increase the costs of small entities that manufacture or import textile fiber products. Therefore, based on available information, the Commission certifies that amending the Rules as proposed will not have a significant economic impact on a substantial number of small businesses. Although the Commission certifies under the RFA that the proposed amendment would not, if promulgated, have a significant impact on a substantial number of small entities, the Commission has determined, nonetheless, that it is appropriate to publish an IRFA to inquire into the impact of the proposed amendment on small entities. Therefore, the Commission has prepared the following analysis:

A. Description of the Reasons That Action by the Agency Is Being Taken

The Commission proposes amending the Rules to incorporate an updated version of the standard establishing generic fiber names to provide covered entities with greater flexibility in complying with the Rules' disclosure requirements.

B. Statement of the Objectives of, and Legal Basis for, the Proposed Amendment

The Textile Act authorizes the Commission to implement its requirements through the issuance of rules. The proposed amendment would incorporate the updated ISO standard 2076:2013(E) into the Textile Rules, and provide covered entities with additional labeling options (*i.e.,* to market products covered by the Textile Rules that are made from generic fibers defined in ISO 2076:2013(E) but not otherwise defined) without imposing new burdens or additional costs.

C. Small Entities To Which the Proposed Amendments Will Apply

The Rules apply to various segments of the textile fiber product industry, including manufacturers and wholesalers of textile apparel products. Under the Small Business Size Standards issued by the Small Business Administration, textile apparel manufacturers qualify as small businesses if they have 500 or fewer

[13] *See* 16 CFR 1.26(b)(5).

[14] 5 U.S.C. 601–612.

[15] 5 U.S.C. 605.

employees. Clothing wholesalers qualify as small businesses if they have 100 or fewer employees. The Commission's staff has estimated that approximately 10,744 textile fiber product manufacturers and importers are covered by the Rules' disclosure requirements.[16] A substantial number of these entities likely qualify as small businesses. The Commission estimates that the proposed amendment will not have a significant impact on small businesses because it imposes no new obligations.

D. Projected Reporting, Recordkeeping, and Other Compliance Requirements, Including Classes of Covered Small Entities and Professional Skills Needed To Comply

As explained earlier in this document, the proposed amendment would incorporate the updated ISO standard 2076:2013(E) into the Textile Rules, thus providing greater flexibility to companies covered by the Rules. The proposed amendment would impose no new reporting, recordkeeping, or other compliance requirements. The small entities potentially covered by the proposed amendment will include all such entities subject to the Rules.

E. Duplicative, Overlapping, or Conflicting Federal Rules

The Commission has not identified any other federal statutes, rules, or policies that would duplicate, overlap, or conflict with the proposed amendment.

F. Significant Alternatives to the Proposed Amendment

The Commission has not proposed any specific small entity exemption or other significant alternatives because the proposed amendment would not impose any new requirements or compliance costs.

VI. Paperwork Reduction Act

The Rules contain reporting requirements that constitute information collection requirements under the Paperwork Reduction Act (PRA).[17] The Office of Management and Budget (OMB) has approved the Rule's existing information collection requirements through May 31, 2021 (OMB Control No. 3084–0101). The proposed amendment does not impose any additional collection of information requirements.

IX. Incorporation by Reference

Consistent with 5 U.S.C. 552(a) and 1 CFR part 51, the Commission proposes to incorporate the specifications of the following standard issued by the International Organization of Standardization (ISO): ISO 2076:2013(E), which lists the generic names used to designate the different categories of man-made fibres, based on a main polymer, currently manufactured on an industrial scale for textile and other purposes, together with the distinguishing attributes that characterize them.

This ISO standard is reasonably available to interested parties. Members of the public can obtain copies of ISO 2076:2013(E) from the American National Standards Institute, 25 West 43rd Street, Fourth Floor, New York, NY 10036–7417; (212) 642–4900; *isot@ansi.org; https://www.ansi.org.* This ISO standard is also available for inspection at the FTC Library, (202) 326–2395, Federal Trade Commission, Room H–630, 600 Pennsylvania Avenue NW, Washington, DC 20580.

VIII. Proposed Rule Language

List of Subjects in 16 CFR Part 303

Advertising, Incorporation by reference, Labeling, Recordkeeping, Textile fiber products.

PART 303—RULES AND REGULATIONS UNDER THE TEXTILE FIBER PRODUCTS IDENTIFICATION ACT

■ 1. The authority citation for part 303 continues to read:

Authority: 15 U.S.C. 70 *et seq.*

■ 2. Amend § 303.7 by revising the introductory text to read as follows:

§ 303.7 Generic names and definitions for manufactured fibers.

Pursuant to the provisions of section 7(c) of the Act, the Commission hereby establishes the generic names for manufactured fibers, together with their respective definitions, set forth in this section, and the generic names for manufactured fibers, together with their respective definitions, set forth in International Organization for Standardization ISO 2076:2013(E), ''Textiles—Man-made fibres—Generic names.'' International Organization for Standardization ISO 2076:2013(E), ''Textiles—Man-made fibres—Generic names,'' Sixth edition, November 15, 2013, is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Federal Trade Commission must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at the Federal Trade Commission, 600 Pennsylvania Ave. NW, Room H–630, Washington, DC 20580, (202) 326–2222, and is available from the American National Standards Institute, 25 West 43rd Street, Fourth Floor, New York, NY 10036–7417; (212) 642–4900; *isot@ansi.org; https://www.ansi.org.* It is also available for inspection 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 *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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By direction of the Commission.

April J. Tabor,

Acting Secretary

[FR Doc. 2020–02759 Filed 2–14–20; 8:45 am]

BILLING CODE 6750–01–P

[16] 83 FR 2992, 2993 (Jan. 22, 2018).

[17] 44 U.S.C. 3501 *et seq;* 5 CFR 1320.3(c).

AMERICAN BATTLE MONUMENTS COMMISSION

36 CFR Part 404

RIN 3263–AA01

ABMC FOIA Regulation

AGENCY: American Battle Monuments Commission.

ACTION: Proposed rule.

SUMMARY: The American Battle Monuments Commission (ABMC) is proposing to revise its procedures and guidelines for compliance with the Freedom of Information Act (FOIA) to incorporate changes required by the FOIA Improvement Act of 2016 and applicable Department of Justice Office of Information Policy guidance.

DATES: Comments must be received by March 19, 2020.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.*

Follow the instructions for submitting comments. All submissions received must include the agency name and docket number or RIN for this document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Edwin L. Fountain, General Counsel, American Battle Monuments Commission, 2300 Clarendon Boulevard, Suite 500, Arlington VA 22201, *fountaine@abmc.gov*.

SUPPLEMENTARY INFORMATION: The authority for this rulemaking is Section 3 of the FOIA Improvement Act of 2016, Public Law 114–185, 5 U.S.C. 552 note, which requires agencies to issue regulations on procedures for the disclosure of records under FOIA in accordance with that Act.

Changes Proposed By ABMC in This Rulemaking

This action updates and revises ABMC's procedures and guidelines for compliance with FOIA. The revisions to the rule:

- Update the description of and contact information for ABMC and the ABMC FOIA Office.
- Require ABMC to make available for public inspection in an electronic format records that have been requested three or more times.
- Set forth verification of identity requirements for requesters making a request for records about himself or another individual.
- Outline procedures for consultation, referral, and coordination with other agencies when appropriate.
- Update procedures and time periods for appeals of denials of requests.
- Notify requesters of their right to seek dispute resolution services from the Office of Government Information Services.

Regulatory Procedures

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

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, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule benefits the public and the United States Government by providing clear procedures for members of the public, contractors, and employees to follow with regard to the ABMC privacy program. This rule is not a significant regulatory action under E.O. 12866.

Executive Order 13771, Reducing Regulations and Controlling Regulatory Costs

This proposed rule is not expected to be subject to the requirements of E.O. 13771 (82 FR 9339, February 3, 2017) because this proposed rule is not significant under E.O. 12866.

Unfunded Mandates Reform Act

This rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments.

Public Law 96–354, Regulatory Flexibility Act

The ABMC certifies this proposed rule is not subject to the Regulatory Flexibility Act (5 U.S.C. Ch. 6) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. Therefore, the Regulatory Flexibility Act, as amended, does not require ABMC to prepare a regulatory flexibility analysis.

Executive Order 13132, Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule will not have a substantial effect on the States; the relationship between the National Government and the States; or the distribution of power and responsibilities among the various levels of Government.

Public Law 96–511, Paperwork Reduction Act

It has been determined that this rule does not impose reporting or record keeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Dated: February 10, 2020.

Robert J. Dalessandro,

Deputy Secretary, ABMC.

List of Subjects in 36 CFR Part 404

Freedom of Information Act.

For the reasons stated in the preamble, ABMC proposes to revise 36 CFR part 404 to read as follows:

Title 36: Parks, Forests, and Public Property

PART 404—PROCEDURES AND GUIDELINES FOR COMPLIANCE WITH THE FREEDOM OF INFORMATION ACT

Sec
404.1 General.
404.2 Authority and functions.
404.3 Organization.
404.4 Access to information.
404.5 Inspection and copying.
404.6 Definitions.
404.7 Fees to be charged—general.
404.8 Fees to be charged—categories of requesters.
404.9 Miscellaneous fee provisions.
404.10 Waiver or reduction of charges.

Authority: FOIA Improvement Act of 2016, Pub. L. 114–185, 5 U.S.C. 552 note.

§ 404.1 General.

This information is furnished for the guidance of the public and in compliance with the requirements of the Freedom of Information Act (FOIA), 5 U.S.C. 552, as amended. Nothing in this subpart shall be construed to entitle any person to any service or to the disclosure of any record to which such person is not entitled under the FOIA. These rules should be read in conjunction with the text of the FOIA and the Uniform Freedom of Information Fee Schedule and Guidelines published by the Office of Management and Budget (''OMB Guidelines'').

§ 404.2 Authority and functions.

The general functions of the American Battle Monuments Commission (ABMC or Commission), as provided by statute, 36 U.S.C. 2101 *et seq.,* are to build and maintain suitable memorials commemorating the service of American Armed Forces and to maintain permanent American military cemeteries in foreign countries.

§ 404.3 Organization.

(a) *Personnel.* (1) The Commission is composed of not more than 11 members appointed by the President.

(2) The day to day operation of the Commission is under the direction of a Secretary appointed by the President.

(3) Principal officials subordinate to the Secretary include the Deputy Secretary, Chief Operating Officer, Chief of Staff, Executive Officer, Chief Financial Officer, Chief of Human Resources and Administration, Chief Information Officer, Director of Cemetery Operations, Executive Engineer, General Counsel, and Public Affairs Officer.

(4) The Commission also creates temporary offices when tasked with

major additional responsibilities not of a permanent nature.

(b) *Locations.* (1) The principal office of the American Battle Monuments Commission is located at 2300 Clarendon Boulevard, Suite 500, Arlington, VA 22201, (703) 696–6900.

(2) The American Battle Monuments Commission maintains an overseas field office in Paris, France, and cemetery offices at 25 locations in Belgium, France, Italy, Luxembourg, Mexico, the Netherlands, Panama, the Philippines, Tunisia, and the United Kingdom.

§ 404.4 Access to information.

(a) *Contact information.* (1) Individuals wishing to file a request under the Freedom of Information Act (FOIA) should address their request in writing to the FOIA Office, American Battle Monuments Commission, 2300 Clarendon Boulevard, Suite 500, Arlington, VA 22201, or to *FOIA@abmc.gov,* or via *https://www.foia.gov.*

(2) The American Battle Monuments Commission makes available information pertaining to Commission matters within the scope of 5 U.S.C. 552(a)(2), including records that have been requested three or more times, by publishing them electronically at the ABMC home page at *https://www.abmc.gov/foia.* Additional information may be found on the National FOIA Portal at *https://www.foia.gov. Note:* The *ABMC.gov* site provides all of the information the Commission has regarding burials at its cemeteries. ABMC does not have service records, casualty lists, or information on burials within the United States.

(b) *Requests.* (1) Requesters must provide contact information, such as their phone number, email address, and/or mailing address, to assist ABMC in communicating with them and providing released records.

(2)(A) Requests for records must reasonably describe the records sought. Requesters must describe the records sought in sufficient detail to enable agency personnel to locate them with a reasonable amount of effort. To the extent possible, requesters should include specific information that may help ABMC identify the requested records, such as the date, title or name, author, recipient, subject matter, case number, file designation, or reference number. Before submitting their requests, requesters may contact the ABMC FOIA Assistant or FOIA Public Liaison to discuss the records they seek and to receive assistance in describing the records.

(B) If a request does not reasonably describe the records sought, response to the request may be delayed. If, after receiving a request, ABMC determines that the request does not reasonably describe the records sought, ABMC must inform the requester what additional information is needed or why the request is otherwise insufficient. Requesters who are attempting to reformulate or modify such a request may discuss their request with the FOIA Assistant or FOIA Public Liaison.

(3) Requests may specify the preferred form or format (including electronic formats) for the records sought. ABMC will accommodate the request if the record is readily reproducible in that form or format.

(c) *Responses to requests.* (1) The ABMC FOIA Office is responsible for responding to FOIA requests. Upon receipt of any perfected request for records, the FOIA Office will determine within 20 days (excepting Saturdays, Sundays and legal public holidays) of the date the request is received in the FOIA Office whether it is appropriate to grant the request and will immediately provide written notification to the person making the request.

(2) ABMC responds to requests in the order of receipt, using multitrack processing. Tracks include simple, and complex, based on whether unusual circumstances apply (see paragraph (d) of this section), the volume of potential records, the need for consultation or referral, and the amount of work or time needed to process the request.

(3) ABMC will acknowledge requests with a tracking number, summary of the request, estimated completion dates, track information, the opportunity to narrow or modify the scope, and contact information for the FOIA Public Liaison.

(4) In determining which records are responsive to a request, ABMC ordinarily will include only records in its possession as of the date that it begins its search. If any other date is used, ABMC must inform the requester of that date.

(d) *Extending time limits.* If the ABMC FOIA Office determines that unusual circumstances apply to the processing of a request, and provides timely written notice to the requester, ABMC may extend the time limits prescribed in paragraphs (c) and (h) of this section for not more than 10 days (excepting Saturdays, Sundays, or legal public holidays). Where unusual circumstances merit an extension of more than 10 working days, ABMC will provide the requester with an opportunity to modify the request or arrange an alternative time period for processing the original or modified request.

(1) As used herein, but only to the extent reasonably necessary to the proper processing of the particular request, the term unusual circumstances means:

(A) The need to search for and collect the requested records from establishments that are separated from the office processing the request;

(B) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(C) The need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the agency which have a substantial subject matter interest therein.

(2) Extensions will be by written notice to the persons making the request. The notice of extension will set forth the reasons for the extension and the date the determination is expected, and will notify the requester of the right to seek assistance from ABMC's FOIA Public Liaison to resolve any disputes between the requester and ABMC, or to seek dispute resolution services from the Office of Government Information Services.

(3) Modification and aggregation of requests. Before issuing a written notice extending time limits, the agency shall provide the person an opportunity to limit the scope of the request so that it may be processed within that time limit or an opportunity to arrange with the agency an alternative time frame for processing the request or a modified request.

(4) When ABMC reasonably believes that a requester, or a group of requestors acting in concert, has submitted requests that constitute a single request, involving clearly related matters, ABMC may aggregate those requests for purposes of this paragraph. One element to be considered in determining whether a belief would be reasonable is the time period over which the requests have occurred.

(5) If ABMC fails to comply with the extended time limit, it may not charge search fees (or for requesters with preferred fee status, may not charge duplication fees), except if unusual circumstances apply and more than 5000 pages are necessary to respond to the request, ABMC may charge search fees (or, for requesters in preferred fee status, may charge duplication fees) *if* timely written notice has been made to the requester and ABMC has discussed with the requester (or made not less than 3 good-faith attempts to do so) how the requester could effectively limit the scope of the request.

(6) If a court determines that exceptional circumstances exist, ABMC's failure to comply with a time limit shall be excused for the length of time provided by the court order. Refusal by the person to reasonably modify the request or arrange such an alternative time frame shall be considered as a factor in determining whether exceptional circumstances exist.

(e) *Consultation, referral, and classified information.* When reviewing records located in response to a request, ABMC will determine whether another agency of the Federal Government is better able to determine whether the record is exempt from disclosure under the FOIA. As to any such record, the ABMC must proceed in one of the following ways:

(1) Consultation. When ABMC records contain within them information of interest to another agency, ABMC should typically consult with that other agency prior to making a release determination.

(2) Referral. When an ABMC record originated with a different agency or contains significant information that originated with a different agency, or when ABMC believes that a different agency is best able to determine whether to disclose a record, ABMC typically should refer the responsibility for responding to the request regarding that record to that agency. When ABMC refers any part of the responsibility for responding to a request to another agency, it must document and maintain a copy of the record, and notify the requester of the referral, informing the requester of the name of the agency and FOIA contact information.

(3) Classified information. On receipt of any request involving classified information, ABMC must determine whether the information is currently and properly classified in accordance with applicable classification rules. ABMC must refer the responsibility for responding to the request regarding that information to the agency that classified the information, or that should consider the information for classification.

(f) *Expedited processing.* (1) Requests and appeals will be taken out of order and given expedited treatment whenever it is determined that they involve:

(i) Circumstances in which the lack of expedited treatment could reasonably be expected to pose an imminent threat to the life or physical safety of an individual;

(ii) An urgency to inform the public about an actual or alleged federal government activity, beyond the public's right to know about government activity generally, if made by a person primarily engaged in disseminating information;

(iii) The loss of substantial due process rights; or

(iv) A matter of widespread and exceptional media interest in which there exist possible questions about the government's integrity which affect public confidence.

(2) A request for expedited processing may be made at the time of the initial request for records or at any later time. A request must include a statement, certified to be true and correct to the best of that person's knowledge and belief, explaining in detail the basis for requesting expedited processing.

(3) Within 10 days of receipt of a request for expedited processing, ABMC will decide whether to grant it and will notify the requester of the decision. If a request for expedited treatment is granted, the request will be given priority and will be processed as soon as practicable. If a request for expedited processing is denied, any appeal of that decision will be acted on expeditiously.

(g) *Grants and denials of requests.* (1) Once ABMC determines it will grant a request in full or in part, it shall notify the requester in writing. ABMC must also inform the requester of any fees charged under § 10 of this subpart and must disclose the requested records to the requester promptly upon payment of any applicable fees. ABMC must inform the requester of the availability of its FOIA Public Liaison to offer assistance.

(2) ABMC may provide interim releases for voluminous requests.

(3) If ABMC determines that a full disclosure of a requested record is not possible, it will consider whether partial disclosure of information is possible. Records disclosed in part will be marked clearly to show the amount of information deleted and the exemption under which the deletion was made, unless doing so would harm an interest protected by an applicable exemption. The location of the information deleted will also be indicated on the record, if technically feasible.]

(4) If the request is denied, in part or in full, the written notification to the requester shall include the reasons for the denial and the estimated volume withheld (unless indicated via markings, or if providing such an estimate would harm an interest protected by an exemption). The notification must inform the requester of:

(i) The requester's right to seek assistance from ABMC's FOIA Public Liaison;

(2) The requester's right to lodge an appeal with ABMC within 90 days after the date of the denial; and

(3) The requester's right to seek dispute resolution services from the Office of Government Information Services (OGIS).

(h) *Appeals.* Appeals shall be set forth in writing within 90 days of receipt of a denial and addressed to the FOIA Office at the address specified in paragraph (a) of this section. The appeal should clearly identify the agency determination that is being appealed and the assigned request number. To facilitate handling, the requester should mark both the appeal letter and envelope, or subject line of the electronic transmission, ''Freedom of Information Act Appeal.'' The appeal shall include a statement explaining the basis for the appeal. Appeals will be adjudicated by the ABMC Secretary, or his designee, and the adjudication will be set forth in writing within 20 days of receipt of the appeal in the ABMC FOIA Office (excepting Saturdays, Sundays, and legal public holidays). If, on appeal, the denial is upheld in whole or in part, the written determination will also contain a notification of the provisions for judicial review and contact information for OGIS dispute resolution services. An appeal ordinarily will not be adjudicated if the request becomes a matter of FOIA litigation.

§ 404.5 Inspection and copying.

When a request for information has been approved pursuant to § 404.4, the person making the request may make an appointment to inspect or copy the materials requested during regular business hours by writing or telephoning the FOIA Officer at the address or telephone number listed in § 404.4(b). Such materials may be copied and reasonable facilities will be made available for that purpose. Copies of individual pages of such materials will be made available at the price per page specified in § 404.7(d); however, the right is reserved to limit to a reasonable quantity the copies of such materials which may be made available in this manner when copies also are offered for sale by the Superintendent of Documents.

§ 404.6 Definitions.

For the purpose of these regulations:

(a) All the terms defined in the Freedom of Information Act apply.

(b) The term *direct costs* means those expenditures that ABMC actually incurs in searching for and duplicating (and in the case of commercial requesters, reviewing) documents to respond to a FOIA request. Direct costs include, for

example, the salary of the employee performing work (the basic rate of pay for the employee plus 16 percent of that rate to cover benefits) and the cost of operating duplicating machinery. Not included in direct costs are overhead expenses such as costs of space, and heating or lighting the facility in which the records are stored.

(c) The term *search* means the process of looking for and retrieving records or information responsive to a request. It includes page-by-page or line-by-line identification of information within records and also includes reasonable efforts to locate and retrieve information from records maintained in electronic form or format. ABMC employees should ensure that searching for material is done in the most efficient and least expensive manner so as to minimize costs for both the agency and the requester. For example, employees should not engage in line-by-line search when merely duplicating an entire document would prove the less expensive and quicker method of complying with a request. Search should be distinguished, moreover, from review of material in order to determine whether the material is exempt from disclosure (see paragraph (f) of this section).

(d) The term *duplication* means the making of a copy of a document, or of the information contained in it, necessary to respond to a FOIA request. Such copies can take the form of paper, microform, audio-visual materials, or electronic records (*e.g.,* magnetic tape or disk), among others. The requester's specified preference of form or format of disclosure will be honored if the record is readily reproducible in that format.

(e) The term *review* refers to the process of examining documents located in response to a request to determine whether any portion of any document located is permitted to be withheld. It also includes processing any documents for disclosure, *e.g.,* doing all that is necessary to excise them and otherwise prepare them for release. Review does not include time spent resolving general legal or policy issues regarding the application of exemptions.

(f) The term *commercial use request* refers to a request from or on behalf of one who seeks information for a use or purpose that furthers the commercial, trade, or profit interests of the requester or the person on whose behalf the request is made. In determining whether a requester properly belongs in this category, ABMC must determine the use to which a requester will put the documents requested. Moreover, where an ABMC employee has reasonable cause to doubt the use to which a requester will put the records sought, or where that use is not clear from the request itself, the employee should seek additional clarification before assigning the request to a specific category.

(g) The term *educational institution* refers to a school that operates a program of scholarly research. A requester in this fee category must show that the request is made in connection with his or her role at the educational institution. Agencies may seek verification from the requester that the request is in furtherance of scholarly research and agencies will advise requesters of their placement in this category.

(h) The term *non-commercial scientific institution* refers to an institution that is not operated on a commercial basis (as that term is referenced in paragraph (g) of this section), and that is operated solely for the purpose of conducting scientific research the results of which are not intended to promote any particular product or industry.

(i) The term *representative of the news media* refers to any person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience. The term ''news'' means information that is about current events or that would be of current interest to the public. Examples of news media entities include television or radio stations that broadcast news to the public at large, and publishers of periodicals that disseminate ''news'' and make their products available through a variety of means to the general public, including news organizations that disseminate solely on the internet. ''Freelance'' journalists who demonstrate a solid basis for expecting publication through a news media entity will be considered as a representative of the news media. A publishing contract would provide the clearest evidence that publication is expected; however, agencies can also consider a requester's past publication record in making this determination. Agencies will advise requesters of their placement in this category. A request for records supporting the news-dissemination function of the requester will not be considered to be for a commercial use.

§ 404.7 Fees to be charged—general.

ABMC shall charge fees that recoup the full allowable direct costs it incurs. ABMC will collect all applicable fees before sending copies of records to the requester. Moreover, it shall use the most efficient and least costly methods to comply with requests for documents made under the FOIA. ABMC may recover the cost of searching for and reviewing records even if there is ultimately no disclosure of records.

(a) *Manual searches for records.* ABMC will charge at the salary rate(s) (*i.e.,* basic pay plus 16 percent) of the employee(s) making the search.

(b) *Computer searches for records.* ABMC will charge at the salary rate(s) (*i.e.,* basic pay plus 16 percent) of the employee(s) making the search. Before assessing fees associated with creating a new computer program, ABMC will ensure that requester is first notified and agrees to pay such fees, pursuant to sub-paragraph (g)(3) of this section.

(c) *Review of records.* Only requesters who are seeking documents for commercial use may be charged for time spent reviewing records to determine whether they are exempt from mandatory disclosure. Charges may be assessed only for the initial review; *i.e.,* the review undertaken the first time ABMC analyzes the applicability of a specific exemption to a particular record or portion of a record. Records or portions of records withheld in full under an exemption that is subsequently determined not to apply may be reviewed again to determine the applicability of other exemptions not previously considered. The costs for such a subsequent review is assessable.

(d) *Duplication of records.* Records will be duplicated at a rate of $.10 per page. For copies prepared by computer, such as tapes or printouts, ABMC shall charge the actual cost, including operator time, of production of the tape or printout. For other methods of reproduction or duplication, ABMC will charge the actual direct costs of producing the document(s). If ABMC estimates that duplication charges are likely to exceed $25, it shall notify the requester of the estimated amount of fees, unless the requester has indicated in advance his willingness to pay fees as high as those anticipated. Such a notice shall offer a requester the opportunity to confer with agency personnel with the object of reformulating the request to meet his or her needs at a lower cost.

(e) *Other charges.* (1) When it elects to charge them, ABMC will recover the full costs of providing services such as certifying that records are true copies or sending records by special methods such as express mail.

(2) For requests that require the retrieval of records stored by an agency at a Federal records center operated by the National Archives and Records Administration (NARA), ABMC will

charge additional costs in accordance with the Transactional Billing Rate Schedule established by NARA.

(f) *Payment of fees.* Remittances shall be in the form either of a personal check or bank draft drawn on a bank in the United States, or a postal money order. Remittances shall be made payable to the order of the Treasury of the United States and mailed to the FOIA Officer, American Battle Monuments Commission, 2300 Clarendon Blvd., Suite 500, Arlington, VA 22201. A receipt for fees paid will be given upon request.

(g) *Restrictions on assessing fees.* With the exception of requesters seeking documents for a commercial use, ABMC will provide the first 100 pages of duplication and the first 2 hours of search time without charge. Moreover, ABMC will not charge fees to any requester, including commercial use requesters, if the cost of collecting a fee would be equal to or greater than the fee itself.

(1) The elements to be considered in determining the cost of collecting a fee are the administrative costs of receiving and recording a requester's remittance, and processing the fee for deposit in the Treasury Department's special account.

(2) For purposes of these restrictions on assessment of fees, the word *pages* refers to paper copies of 8½ x 11 or 11 x 14. Thus, requesters are not entitled to 100 microfiche or 100 computer disks, for example. A microfiche containing the equivalent of 100 pages or 100 pages of computer printout, does meet the terms of the restriction.

(3) Similarly, the term *search time* in this context has as its basis, manual search. To apply this term to searches made by computer, ABMC will determine the hourly cost of operating the central processing unit and the operator's hourly salary plus 16 percent. When the cost of search equals the equivalent dollar amount of two hours of the salary of the person performing the search, *i.e.,* the operator, ABMC will begin assessing charges.

§ 404.8 Fees to be charged—categories of requesters.

For purposes of assessing fees, the FOIA establishes four categories of requesters: Commercial use requesters, educational and non-commercial scientific institution requesters; news media requesters, and all other requesters.

(a) *Commercial use requesters.* When ABMC receives a request for documents for commercial use, it will assess charges that recover the full direct costs of searching for, reviewing for release, and duplicating the records sought. Commercial use requesters are not entitled to 2 hours of free search time nor 100 free pages of reproduction of documents.

(b) *Educational and noncommercial scientific institution requesters.* Requesters in this category who meet the criteria in § 404.6(g) or (h) are entitled to two free hours of search time and the first 100 pages of duplication without charge. To be eligible for inclusion in this category, a requester must show that the request is authorized by and under the auspices of a qualifying institution and that the records are not sought for a commercial use, but are sought in furtherance of scholarly (if the request is from an educational institution) or scientific (if the request is from a non-commercial scientific institution) research.

(c) *Requesters who are representatives of the news media.* Requesters in this category who meet the criteria in § 404.6(i) are entitled to two free hours of search time and the first 100 pages of duplication without charge. To be eligible for inclusion in this category, a requester must show that the records are not sought for a commercial use, but are sought in furtherance of the news dissemination function of the requester.

(d) *All other requesters.* ABMC shall charge requesters who do not fit into any of the categories above fees that recover the full reasonable direct cost of searching for and reproducing records that are responsive to the request, except that the first 100 pages of reproduction and the first 2 hours of search time shall be furnished without charge.

§ 404.9 Miscellaneous fee provisions.

(a) *Charging interest—notice and rate.* ABMC may begin assessing interest charges on an unpaid bill starting on the 31st day following the day on which the billing was sent. The fact that the fee has been received by ABMC within the 30-day grace period, even if not processed, will suffice to stay the accrual of interest. Interest will be at the rate prescribed in 31 U.S.C. 3717 and will accrue from the date of the billing.

(b) *Charges for unsuccessful search.* ABMC may assess charges for time spent searching, even if it fails to locate the records or if records located are determined to be exempt from disclosure. If ABMC estimates that search charges are likely to exceed $25, it shall notify the requester of the estimated amount of fees, unless the requester has indicated in advance his willingness to pay fees as high as those anticipated. Such a notice shall offer the requester the opportunity to confer with agency personnel with the object of reformulating the request to meet his or her needs at a lower cost.

(c) *Aggregating requests.* A requester may not file multiple requests at the same time, each seeking portions of a document or documents, solely in order to avoid payment of fees. When ABMC reasonably believes that a requester, or a group of requestors acting in concert, has submitted requests that constitute a single request, involving clearly related matters, ABMC may aggregate those requests and charge accordingly. One element to be considered in determining whether a belief would be reasonable is the time period over which the requests have occurred.

(d) *Advance payments.* ABMC may not require a requester to make an advance payment, *i.e.,* payment before work is commenced or continued on a request, unless:

(1) ABMC estimates or determines that allowable charges that a requester may be required to pay are likely to exceed $250. Then, ABMC will notify the requester of the likely cost and obtain satisfactory assurance of full payment where the requester has a history of prompt payment of FOIA fees, or require an advance payment of an amount up to the full estimated charges in the case of requesters with no history of payment; or

(2) A requester has previously failed to pay a fee charged in a timely fashion (*i.e.,* within 30 days of the date of the billing). Then, ABMC may require the requester to pay the full amount owed plus any applicable interest as provided above or demonstrate that he or she has, in fact, paid the fee, and to make an advance payment of the full amount of the estimated fee before the agency begins to process a new request or a pending request from that requester.

(3) When ABMC acts under paragraph (d)(1) or (2) of this section, the administrative time limits prescribed in the FOIA, 5 U.S.C. 552(a)(6) (*i.e.,* 20 working days from receipt of initial requests and 20 working days from receipt of appeals from initial denial, plus permissible extensions of these time limits), will begin only after ABMC has received fee payments described in paragraphs (d)(1) and (2) of this section.

(e) *Effect of the Debt Collection Act.* ABMC will comply with provisions of the Debt Collection Act of 1982 (Pub. L. 97–365), including disclosure to consumer reporting agencies and use of collection agencies, where appropriate, to encourage repayment.

(e) *Tolling.* If the requester has indicated a willingness to pay some designated amount of fees, but the ABMC estimates that the total fee will exceed that amount, ABMC will toll the

processing of the request when it notifies the requester of the estimated fees in excess of the amount the requester has indicated a willingness to pay. The agency will inquire whether the requester wishes to revise the amount of fees the requester is willing to pay or modify the request. Once the requester responds, the time to respond will resume from where it was at the date of the notification.

(f) *Reducing costs.* At any time a request may contact the ABMC FOIA Public Liaison or other FOIA professional to assist in reformulating a request to meet the requester's needs at a lower cost.

§ 404.10 Waiver or reduction of charges.

Requesters may seek a waiver of fees by submitting a written application demonstrating how disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

(a) ABMC will waive its fees in whole or in part when it determines, based on all available information, that the following factors are satisfied:

(1) Disclosure of the requested information will shed light on identifiable operations or activities of the Federal Government with a connection that is direct and clear, not remote or attenuated.

(2) The disclosure will contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester. ABMC will consider the requester's expertise in the subject area as well as the requester's ability and intention to effectively convey information to the public. ABMC will presume that a representative of the news media satisfies this consideration.

(3) The disclosure is not primarily in the commercial interest of the requester. Requesters will be given an opportunity to provide explanatory information regarding this consideration. ABMC ordinarily will presume that when a news media requester has satisfied factors in paragraphs (a)(1) and (a)(2) of this section, the request is not primarily in the commercial interest of the requester.

(b) Where only some of the records to be released satisfy the requirements for a waiver of fees, a waiver must be granted for those records.

(c) Requests for a waiver or reduction of fees should be made when the request is first submitted to the agency and should address the criteria referenced above. A requester may submit a fee waiver request at a later time so long as the underlying record request is pending or on administrative appeal. When a requester who has committed to pay fees subsequently asks for a waiver of those fees and that waiver is denied, the requester must pay any costs incurred up to the date the fee waiver request was received.

[FR Doc. 2020–03016 Filed 2–14–20; 8:45 am]

BILLING CODE 6120–01–P

POSTAL REGULATORY COMMISSION

39 CFR Chapter III

[Docket No. RM2020–4; Order No. 5422]

Amendments to Rules of Practice

AGENCY: Postal Regulatory Commission.

ACTION: Advanced notice of proposed rulemaking.

SUMMARY: The Commission seeks input from the public about what regulations promulgated by the Commission may be necessary to carry out certain statutory responsibilities related to the letter monopoly, specifically those instances where the letter monopoly does not apply to a mailpiece.

DATES: *Comments are due:* April 7, 2020.

ADDRESSES: For additional information, Order No. 5422 can be accessed electronically through the Commission's website at *https://www.prc.gov.* Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

The Commission issues this advance notice of proposed rulemaking to seek input from the public about what regulations promulgated by the Commission may be necessary to carry out the requirements of 39 U.S.C. 601, ''Letters carried out of the mail,'' which, as explained in greater detail below, describes when the letter monopoly does not apply to a mailpiece.[1]

II. Background

The Postal Service has exclusive rights in the carriage and delivery of letters under certain circumstances. This letter monopoly is codified in the Private Express Statutes (PES), which are a group of civil and criminal statutes that make it unlawful for any entity other than the Postal Service to send or carry letters. *See* 18 U.S.C. 1693–1699; 39 U.S.C. 601–606.[2]

Section 601 provides specific instances (exceptions) where letters may be carried out of the mail (*i.e.,* not subject to the letter monopoly). These statutory exceptions include letters charged more than six times the current rate for the first ounce of a single-piece first class letter and letters weighing more than 12.5 ounces. *See* 39 U.S.C. 601(b)(1), (b)(2). A ''grandfather clause'' in Section 601(b)(3) also references exceptions from prior Postal Service policies and regulations. The statute also directs the Commission to promulgate any regulations necessary to carry out this section. *See* 39 U.S.C. 601(c).

Prior to the Postal Accountability and Enhancement Act (PAEA) of 2006, the Postal Service issued regulations to define and suspend the PES.[3] These regulations defined the crucial term ''letter'' as ''a message directed to a specific person or address and recorded in or on a tangible object,'' subject to several provisions. 39 CFR 310.1(a). The regulations also described several statutory exceptions to the letter monopoly, such as when the letter accompanies and relates to cargo or when a special messenger is used. *See* 39 CFR 310.3. In addition, the regulations describe administrative suspensions of the PES (39 CFR 310.1(a)(7) n.1, 320), including suspensions for certain data processing materials or for extremely urgent letters. *See* 39 CFR 320.2, 320.6. These regulations were originally promulgated by the Postal Service in 1974 and have been amended several times.[4] In 2003,

[1] The scope of this proceeding and inquiry does not extend to the mailbox monopoly (or mailbox rule), which grants the Postal Service the exclusive ability to deposit mailable matter in a letter box. See 18 U.S.C. 1725.

[2] Although these provisions of the U.S. Code are customarily referred to collectively as the ''Private Express Statutes,'' they do not all relate to private expresses or prohibit carriage of letters out of the mails.

[3] *See* Postal Accountability and Enhancement Act, Public Law 109–435, 120 Stat. 3198 (2006); *see also* 39 CFR 310, 320.

[4] *See* Comprehensive Standards for Permissible Private Carriage, 39 FR 33211 (Sept. 16, 1974).

the President's Commission on the United States Postal Service recommended that the scope of the letter monopoly should be clarified and periodically reviewed by a Postal Regulatory Board.[5]

In 2006, Congress passed PAEA to clarify the limited statutory exemptions to the monopoly.[6] In addition to adding price and weight limits as exceptions (601(b)(1), (b)(2)), Congress also added a ''grandfather clause'' in Section 601(b)(3) to authorize the continuation of private activities that the Postal Service had permitted by regulations to be carried out of the mail. The House Report on the PAEA explains that the clause protects mailers and private carriers who had relied upon the regulations adopted as of the date of the bill. *See id.* at 58. Congress also eliminated the Postal Service's authority to adopt any future regulations creating additional exceptions or defining the scope of the postal monopoly. *See* 39 U.S.C. 401(2), 404a(a)(1), 601. Congress instead gave the Commission the authority to promulgate ''any regulations necessary to carry out this section [601].'' [7] To date, the Commission has not promulgated any regulations pursuant to Section 601(c), and issues this advance notice of proposed rulemaking to explore potential options for doing so now.

III. Issues for Consideration

In the more than 45 years since the Postal Service initially promulgated its regulations, the postal industry has fundamentally changed. The Postal Service recently stated that the ''most significant competitor for First-Class Mail is digital communication, including electronic mail, and other digital technologies such as online bill payment and presentment.'' [8] The USPS Office of Inspector General also released a report citing electronic diversion as a key factor that has affected the First-Class Mail correspondence segment.[9]

Over time there have been several published reports discussing or evaluating the letter monopoly. In a 2007 report, the Federal Trade Commission stated that the monopoly should only be as broad as needed to satisfy the statutory requirement of universal service.[10] The Commission, in response to Section 702 of the PAEA, issued a report on Universal Postal Service and the Postal Monopoly, which traced the history of the monopoly to its current status.[11] The Government Accountability Office reported that narrowing the monopoly could decrease revenues and threaten the universal service obligation, but may also lead to greater efficiencies and innovation.[12] In 2018, the Task Force on the United States Postal System stated that the statutory monopoly business model is increasingly ineffective.[13] In particular, it explained that ''technological changes have significantly reduced the effectiveness of the statutory monopoly business model by undermining the historical barriers to market competition and product substitution.'' *Id.*

The Commission has generally discussed or acknowledged the letter monopoly when reviewing requests to modify the product lists. In such cases, the Commission must consider whether a product is covered by the monopoly. *See* 39 U.S.C. 3642(b)(2). For example, in Docket Nos. MC2012–14 and R2012–8, where the Commission approved a new product as a Market Dominant Negotiated Service Agreement, the Commission acknowledged, without considering the merits of, assertions by the Postal Service that a specific product is subject to the postal monopoly. Order No. 1448 at 6–7.

Specifically in dockets where the Postal Service seeks to classify a product as competitive, it often cites various statutory and regulatory exceptions to the monopoly. For example, in Docket No. MC2012–13, the Postal Service asserted that the contents of Parcel Post are outside the scope of the letter monopoly because: (1) Invoices or receipts accompanying merchandise mailed as Parcel Post are subject to the cargo exception in 39 CFR 310.3(a), (2) incidental, non-addressed, non-personalized advertising may be enclosed pursuant to 39 CFR 320.7, and (3) any letters enclosed would be permitted due to the price exception pursuant to 39 U.S.C. 601(b)(1). Order No. 1411 at 6–7. In another case, the Postal Service acknowledged that a sealed parcel could contain letter material and, therefore, stated it intended to raise prices consistent with 39 U.S.C. 601(b)(1) to avoid the application of the PES.[14] The Commission has acknowledged these past assertions.[15]

In Docket No. MC2013–57, several parties addressed whether the Round-Trip Mailer product, which consists of a round-trip mailing of a disc, was covered by the postal monopoly.[16] In particular, the parties disputed whether the content of the Round-Trip Mailer constitutes a ''letter'' that is subject to the Private Express Statutes. *Id.* Because of a finding on market power, the Commission did not rule on the merits of the monopoly issue. *Id.* at 56. However, the Commission noted that ''[t]he legal and policy issues surrounding the postal monopoly have far-reaching and important implications that go beyond the boundaries of this proceeding.'' *Id.* The Commission further stated that the ''issue may be appropriate for review in a separate proceeding.'' *Id.* The Commission believes it is now time for that separate proceeding.

With this background, the Commission issues this advance notice of proposed rulemaking to consider approaches to fulfilling its statutory

[5] Embracing the Future: Making the Tough Choices to Preserve Universal Mail Service, July 31, 2003, at 71. The President's Commission recommended ''transforming the narrowly focused Postal Rate Commission [ ] into an independent Postal Regulatory Board.'' *Id.* at XIII.

[6] *See* H.R. Rep. No. 109–66 (2005) part 1, at 57. Congress stated that ''the bill clarifies the scope of the statutory monopoly that historically has been defined solely by the [Postal Service].'' *Id.* at 58.

[7] 39 U.S.C. 601(c). Docket Nos. MC2012–14 and R2012–8, Order Approving Addition of Valassis Direct Mail, Inc. Negotiated Service Agreement to the Market Dominant Product List, August 23, 2012, at 6–7 (Order No. 1448) (citing Section 601(c) and stating that the Postal Service no longer has authority to issue regulations interpreting or defining the postal monopoly); *see also* Docket No. MC2012–13, Order Conditionally Granting Request to Transfer Parcel Post to the Competitive Product List, July 20, 2012, at 6–7 (Order No. 1411) (''As a result of the PAEA, the Postal Service no longer has authority to issue regulations interpreting or defining the postal monopoly. The Commission now has the authority to promulgate such regulations.''). Order No. 1411 at 7 n.13.

[8] The U.S. Postal Service Five-Year Strategic Plan FY2020–FY2024, January 7, 2020, at 14.

[9] *See* USPS Office of Inspector General, A New Reality: Correspondence Mail in the Digital Age, March 5, 2018, at 9.

[10] Accounting for Laws that Apply Differently to the United States Postal Service and its Private Competitors: A Report by the Federal Trade Commission, January 16, 2008, at 93.

[11] Report on Universal Service and the Postal Monopoly, December 19, 2008, at 15–84 (USO Report). The USO Report includes, as an appendix, George Mason University's presentation and analysis of the history of the postal monopoly. *See* George Mason University, School of Public Policy, Postal Monopoly Laws: History and Development of the Monopoly on the Carriage of Mail and the Monopoly on Access to Mailboxes, November 2008, at 250 (''[A]ny decision by the Commission interpreting the term letter in section 601 would be considered tantamount to defining the scope of the monopoly.''). *Id.*

[12] U.S. Governmental Accountability Office, U.S. Postal Service, Key Considerations for Potential Changes to USPS's Monopolies, GAO–17–543, June 22, 2017, at 8.

[13] Task Force on the United States Postal Service, United States Postal Service: A Sustainable Path Forward, December 2018, at 33.

[14] *See* Docket No. MC2015–7, Request of the United States Postal Service to Transfer First-Class Mail Parcels to the Competitive Product List, November 14, 2014, Attachment B at 2.

[15] *See* Docket No. MC2015–7, Order Conditionally Approving Transfer, July 20, 2017, at 35 (Order No. 4009); Order No. 1411 at 7.

[16] Docket No. MC2013–57, Order Denying Request, December 23, 2014, at 54–56 (Order No. 2306).

responsibilities under 39 U.S.C. 601(c), including considering whether changes are needed to the regulations concerning the letter monopoly or necessary to carry out Section 601.

The Commission is soliciting comments to identify issues that may be considered when developing regulations to implement 39 U.S.C. 601. *See* 39 U.S.C. 601(c). All relevant comments will be considered. However, the Commission is interested in comments on the following specific issues:

1. Are the statutory requirements of 39 U.S.C. 601(a) clear and concise, or are additional regulations necessary to carry out the intent of the statute?

2. Are the statutory requirements of 39 U.S.C. 601(b) clear and concise, or are additional regulations necessary to carry out the intent of the statute?

3. Is the scope of 39 U.S.C. 601(b)(3)—permitting that the carriage of letters out of the mail provided ''such carriage is within the scope of services described by regulations of the United States Postal Service (including, in particular, sections 310.1 and 320.2–320.8 of title 39 of the Code of Federal Regulations, as in effect on July 1, 2005) that purport to permit private carriage by suspension of the operation of this section (as then in effect)''—sufficiently clear and concise, or are additional regulations necessary to carry out the intent of the statute?

4. Do any terms that currently appear in 39 U.S.C. 601 require further definition?

5. Can consumers and competitors easily determine when a mailpiece is subject to monopoly protections?

6. What is the current effect of the letter monopoly on consumers, small businesses, and competitors?

7. Are the weight and/or price requirements found in 39 U.S.C. 601(b) still relevant?

8. Are the weight and/or price requirements found in 39 U.S.C. 601(b) applied uniformly?

9. Have there been any post-PAEA Postal Service regulations that appear to limit, expand, or otherwise affect the scope of the letter monopoly contrary to law?

10. Is the term ''letter'' clear and concise, or can any improvements be made to the definition? If so, please provide any proposed definitions and explain how the proposed definition may better implement the intent of Congress and affect the scope of the letter monopoly.

11. Do the current statutory and regulatory requirements correctly implement the intent of Congress and advance the public interest, or should consideration be given to any changes that may be implemented by regulation?

12. How might changes to the statutory and regulatory requirements regarding the scope of the letter monopoly affect the financial condition of the Postal Service, competitors of the Postal Service, users of the Postal Service, and/or the general public interest?

13. Are there any social, economic, technological, or other trends that should be taken into account by Congress in considering the scope of the monopoly?

14. Because the Commission is tasked with developing regulations to carry out 39 U.S.C. 601, to what extent should the Commission adopt regulations that replicate, in whole or in part, the Postal Service's regulations that appear at 39 CFR 310.1 and 320.2 through 320.8?

IV. Ordering Paragraphs

It is ordered:

1. Docket No. RM2020–4 is established for the purpose of considering amendments to the Code of Federal Regulations, title 39, chapter III, as discussed in this advance notice of proposed rulemaking.

2. Interested persons may submit comments no later than April 7, 2020.

3. Pursuant to 39 U.S.C. 505, Kenneth E. Richardson is appointed to serve as Public Representative in this proceeding.

4. The Secretary shall arrange for publication of this Order in the **Federal Register**.

By the Commission.

Erica A. Barker,

Secretary.

[FR Doc. 2020–03156 Filed 2–14–20; 8:45 am]

BILLING CODE 7710–FW–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2020–0011; FRL–10005–43–Region 7]

Air Plan Approval; Missouri; Control of Nitrogen Oxide Emissions From Portland Cement Kilns

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Missouri State Implementation Plan (SIP) received on February 15, 2019. The submission revises a Missouri regulation that establishes nitrogen oxide (NO_X) control equipment and NO_X emission levels for Portland cement kilns. Specifically, the revisions add a definition, remove obsolete dates, update references to test methods, clarify rule language, remove unnecessary words, and make other minor edits. These revisions do not impact the stringency of the SIP and do not impact air quality. Approval of these revisions will ensure consistency between State and federally-approved rules.

DATES: Comments must be received on or before March 19, 2020.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–R07–OAR–2020–0011 to *https://www.regulations.gov.* Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received will be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Written Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Tracey Casburn, Environmental Protection Agency, Region 7 Office, Air Quality Planning Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number (913) 551–7016; email address *casburn.tracey@epa.gov.*

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

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VI. Statutory and Executive Order Reviews

I. Written Comments

Submit your comments, identified by Docket ID No. EPA–R07–OAR–2020–0011, at *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the

official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. What is being addressed in this document?

The State revised title 10, division 10 of the code of state regulations, 10 CSR 10–6.380 ''Control of NO_X Emissions from Portland Cement Kilns'', which establishes NO_X control equipment and NO_X emission levels for Portland cement kilns. Specifically, the revisions add a definition, remove obsolete dates, update references to test methods, clarify rule language, remove unnecessary words, and make other minor edits. 10 CSR 10–6.380 is SIP approved in the Code of Federal Regulations at 40 CFR 52.1320(c). The State submitted its revisions to 10 CSR 10–6.380 to the EPA as a SIP revision on February 15, 2019. In this action, the EPA is proposing to approve the revisions. The revisions are administrative in nature and do not impact air quality. The EPA's analysis of the revisions can be found in the technical support document (TSD) included in this docket.

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

The State submission has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submission also satisfied the completeness criteria of 40 CFR part 51, appendix V. The State provided public notice of the revisions from July 30, 2018, to September 6, 2018, and held a public hearing on August 30, 2018. The State received and addressed comments from the EPA. As explained in more detail in the TSD which is part of this docket, the SIP revision submission meets the substantive requirements of the CAA, including section 110 and implementing regulations.

IV. What action is the EPA taking?

The EPA is proposing to amend the Missouri SIP by approving the State's request to revise 10 CSR 10–6.380,''Control of NO_X Emissions From Portland Cement Kilns.'' Approval of these revisions will ensure consistency between State and federally-approved rules. The EPA has determined that these changes will not adversely impact air quality.

The EPA is processing this as a proposed action because we are soliciting comments on the action. Final rulemaking will occur after consideration of any comments.

V. Incorporation by Reference

In this rule, the EPA is proposing to include regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the State's rule as described in the proposed amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 7 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VI. 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, if they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- 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 the National Technology Transfer and Advancement Act (NTTA) because this rulemaking does not involve technical standards; 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).

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

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen oxide, Portland cement kilns.

Dated: February 11, 2020.

James Gulliford,

Regional Administrator, Region 7.

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

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart AA—Missouri

■ 2. In § 52.1320, the table in paragraph (c) is amended by revising entry ''10–6.380'' to read as follows:

§ 52.1320 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MISSOURI REGULATIONS

Missouri citation	Title	State effective date	EPA approval date	Explanation
Missouri Department of Natural Resources				
*	*	*	*	*
Chapter 6—Air Quality Standards, Definitions, Sampling and Reference Methods, and Air Pollution Control Regulations for the State of Missouri				
*	*	*	*	*
10–6.380	Control of NO_X Emissions From Portland Cement Kilns.	2/28/2019	[Date of publication of the final rule in the **Federal Register**], [**Federal Register** citation of the final rule].	
*	*	*	*	*

* * * * *

[FR Doc. 2020–03073 Filed 2–14–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60, 61, and 63

[EPA–R09–OAR–2019–0632; FRL–10004–32–Region 9]

Delegation of New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants for the States of Arizona and Nevada

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve updates to the Code of Federal Regulations delegation tables to reflect the current delegation status of New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants in Arizona and Nevada.

DATES: Comments must be received by March 19, 2020.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2019–0632 at *http://www.regulations.gov,* or via email to *buss.jeffrey@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, 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, 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 *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Jeffrey Buss, EPA Region IX, (415) 947–4152, *buss.jeffrey@epa.gov.*

SUPPLEMENTARY INFORMATION: In the ''Rules and Regulations'' section of this **Federal Register**, the EPA is approving updates to the Code of Federal Regulations delegation tables to reflect the current delegation status of New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants in Arizona and Nevada. We are approving these updates in a direct final action without prior proposal because we believe this action is not controversial. A detailed rationale for the approval is set forth in the direct final rule. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in a subsequent final rule based on this proposed rule. Please note that if the EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, the EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

We do not plan to open a second comment period, so anyone interested in commenting should do so at this time. If we do not receive adverse comments, no further activity is planned. For further information, see please see the direct final action.

Dated: December 23, 2019.

Elizabeth J. Adams,

Director, Air and Radiation Division, Region IX.

[FR Doc. 2020–01729 Filed 2–14–20; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 402

Office of the Secretary

45 CFR Part 102

[CMS–6061–P]

RIN 0938–AT86

Medicare Program; Medicare Secondary Payer and Certain Civil Money Penalties

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would specify how and when CMS must calculate and impose civil money penalties (CMPs) when group health plan (GHP) and non-group health plan (NGHP) responsible reporting entities

(RREs) fail to meet their Medicare Secondary Payer (MSP) reporting obligations in any one or more of the following ways: When RREs fail to register and report as required by MSP reporting requirements; when RREs report as required, but report in a manner that exceeds error tolerances established by the Secretary of the Department of Health and Human Services (the Secretary); when RREs contradict the information the RREs have reported when CMS attempts to recover its payments from these RREs. This proposed rule would also establish CMP amounts and circumstances under which CMPs would and would not be imposed.

DATES: *Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on April 20, 2020.

ADDRESSES: In commenting, please refer to file code CMS–6061–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four 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 (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6061–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6061–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Jacqueline Cipa, (410) 786–3259.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://regulations.gov.* Follow the search instructions on that website to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. Imposition of Civil Money Penalties (CMPs)—Legislative Overview

In 1981, the Congress added section 1128A to the Social Security Act (the Act) (section 2105 of Pub. L. 97–35) to authorize the Secretary of Health and Human Services (the Secretary) to impose civil money penalties (CMPs) and assessments on certain health care facilities, health care practitioners, and other suppliers for noncompliance with rules of the Medicare and Medicaid programs. CMPs and assessments provide an enforcement tool for agencies to use to ensure compliance with statutory and regulatory requirements. These administrative penalties may be imposed in addition to potential criminal or civil penalties.

Since 1981, the Congress has increased both the number and the types of circumstances under which the Secretary may impose CMPs. Some CMP authorities address fraud, misrepresentation, or falsification, while others address noncompliance with programmatic or regulatory requirements. The Secretary has delegated the authority for certain provisions to either the Office of Inspector General (OIG) or Centers for Medicare & Medicaid Services (CMS). (See the October 20, 1994 notice, titled ''Office of Inspector General; Health Care Financing Administration; Statement of Organization, Functions, and Delegations of Authority,'' (58 FR 52967).) A summary of these CMP changes are discussed in this section of this proposed rule.

B. Legislative History

In 1980, the Congress added section 1862(b) of the Act, which defined when Medicare is the secondary payer to certain primary plans. These provisions are known as the Medicare Secondary Payer (MSP) provisions of the Act.

Section 1862(b) of the Act prohibits Medicare from making payment if payment has been made, or can reasonably be expected to be made by any of the following primary plans:

- Group Health Plans (GHPs).
- Workers' compensation plans.
- Liability insurance (including self-insurance).
- No-fault insurance.

Medicare may make conditional payments, subject to Medicare payment rules, in situations where workers' compensation, liability insurance (including self-insurance), or no-fault insurance has not made payment or cannot be expected to make payment promptly. See section 1862(b)(2)(A) of the Act. Any conditional payments that Medicare makes are subject to reimbursement from the primary plan. See section 1862(b)(2)(B) of the Act.

C. Legislative Provisions Regarding Mandatory Reporting Requirements

To enhance enforcement of the MSP provisions, section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173) added paragraphs (7) and (8) to section 1862(b) of the Act. These paragraphs established new mandatory reporting requirements regarding Medicare beneficiaries who have coverage under GHP arrangements as well as for Medicare beneficiaries who receive settlements, judgments, awards or other payment from liability insurance (including self-insurance), no-fault insurance, or workers' compensation (collectively referred to as Non-Group Health Plan, or NGHP). Sections 1862(b)(7)(A) and 1862(b)(8)(F) of the Act define those parties responsible for this reporting (collectively referred to as RREs); they are generally identified as group health insurers or third party administrators or both as well as NGHP applicable plans. RREs are currently required to submit coverage information for Medicare beneficiaries on a quarterly basis through an electronic file submission process that may vary depending upon the number of beneficiary records being reported or updated. This coverage information primarily consists of enough identifying information to uniquely identify the Medicare beneficiary and confirm their beneficiary status, as well as information about the nature of the coverage (such as GHP or NGHP, coverage effective dates, policy limits, settlement amounts, and so forth). These section 111 of MMSEA reporting provisions do not eliminate any other existing statutory provisions or

regulations. Further, these reporting provisions include authority for Medicare to impose CMPs against entities that fail to comply with the section 111 of MMSEA reporting requirements under section 1862(b)(7) or (b)(8) of the Act, and required that GHPs and NGHPs that fail to comply with these reporting requirements shall be subject to a CMP of up to $1,000 for each calendar day of noncompliance.

In 2013, Congress enacted the Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 (the SMART Act, at SSA section 1862(b), and codified at 42 U.S.C. 1395(y)(b)(2). The SMART Act amended section 1862(b)(8)(E) of the Act, which includes the section 111 of MMSEA reporting requirements and describes the enforcement provisions for NGHPs that fail to comply with the reporting requirements. The SMART Act revised section 1862(b)(8)(E) of the Act to state that NGHP applicable plans that fail to comply with the reporting requirements *may* be subject to a civil money penalty of *up to* $1,000 for each calendar day of reporting noncompliance required of NGHP applicable plans under section 1862(b)(8)(E) of the Act. The SMART Act also added section 1862(b)(8)(I) of the Act, which specifically required rulemaking actions regarding the enforcement of CMP provisions under section 1862(b)(8)(E) of the Act.

We note that the SMART Act did not amend any CMP provisions for GHP arrangements that have reporting obligations under section 1862(b)(7) of the Act. Such GHP arrangements remain subject to *mandatory* CMPs of $1,000 per calendar day of noncompliance and per individual for whom submission of information was required. In addition, the SMART Act directed rulemaking for NGHP applicable plans regarding the imposition and non-imposition of CMPs.

We further note that the statutory language speaks to ''individuals,'' though there are situations described that are specifically applicable to Medicare beneficiaries; we have attempted to be consistent with the usage of this statutory terminology but use the term ''beneficiary'' where it is more appropriate.

D. Summary of Public Comments Received on the December 11, 2013 Advanced Notice of Proposed Rulemaking (ANPRM)

In accordance with the rulemaking directed by the SMART Act, on December 11, 2013 (78 FR 75304), we published an advance notice of proposed rulemaking (ANPRM) titled ''Medicare Secondary Payer and Certain Civil Money Penalties.'' The December 2013 ANPRM solicited public comment on specific practices for which CMPs may or may not be imposed for failure to comply with MSP reporting requirements for certain GHP and NGHP arrangements.

We received 34 timely pieces of correspondence in response to the December 2013 ANPRM. In this section of the proposed rule, we provide an analysis of the public comments received by subject area, with a focus on the most common issues raised, and briefly discuss how we propose to address the issues raised by commenters in response to the 2013 ANPRM in this proposed rule.

1. CMPs and ''Good Faith Efforts'' To Obtain Information To Report

Commenters suggested that CMS refrain from imposing CMPs where NGHPs with reporting obligations under section 1862(b)(8) of the Act make ''good faith efforts'' to obtain required information from individuals who are unwilling or unable to provide it. Some ''good faith efforts'' suggested included the following: (1) CMS could accept documentation signed by the individual stating that he, or she is either not a Medicare beneficiary, or will not provide the NGHP entity with his or her Social Security Number (SSN) (full SSN or last 5 digits); and (2) CMS could accept a judicial order establishing that the individual is not required to provide his or her Medicare Beneficiary Identifier (MBI) or SSN to the NGHP entity. We note that concerns about ''good faith efforts'' were received from the NGHP industry and not the GHP industry, which we believe is reflective of fundamental differences between the two industries and the relationships between those plans and the individuals in question. Our understanding is that NGHP applicable plans may be in an adversarial relationship at times with the reportable individual, whereas the reportable individual is typically the client of a GHP.

In response to the comments, we are proposing that we would not assess CMPs against NGHP entities where those entities make efforts as defined in this proposed rule to obtain necessary reporting information. NGHP entities would document their records with their efforts to obtain this reporting information, as we would retain the right to audit such documentation.

2. Determining Noncompliance

Most commenters suggested that ''noncompliance'' with CMS's reporting requirements include failure to—(1) report when an entity is required to report; (2) report all Medicare beneficiaries who are/were plan participants (GHP) or claimants (NGHP); and (3) report when medical care was either claimed or released (as a part of a settlement, judgment, award, or other payment). We generally agree with the suggested concepts and have incorporated them into section II. of this proposed rule involving these reporting requirements.

3. Amounts of CMPs

A number of commenters recommended developing a ''sliding scale'' or ''tiered'' CMP approach, based upon the requirement of the responsible reporting entity (RRE) to obtain the necessary reporting information from these entities. We considered the possibility of incorporating penalty tiers for NGHP entities that have reporting obligations under section 1862(b)(8) of the Act. However, we are not proposing to rely on the intent of the NGHP entity reporting. Instead, we are proposing that we would assign CMP amounts based on the number of times, meaning individuals, a particular entity fails to report, or fails to report correctly. We solicit comment on this proposal, as explained in section II. of this proposed rule.

4. Proposed ''Safe Harbors''

Many commenters suggested that CMS should establish a series of ''safe harbors'' that would preclude the assessment of a CMP. We note that multiple commenters were concerned about non-compliance due to technical issues and wished to define these myriad situations as ''safe harbors.'' In section II. of this proposed rule, we are proposing to employ tolerances related to submissions that contain certain types of errors or mistakes to address these comments, and to only consider performance against those tolerances over time so that a few poor submissions do not necessarily result in the imposition of a CMP. Multiple commenters were also concerned about their ability to obtain all of the required information for reporting and requested safe harbors for non-compliance due to non-cooperation on the part of the reportable individual. This situation has been addressed under ''good faith efforts'' in this section.

5. Develop an Appeals Process

A number of commenters suggested that CMS should develop a formal appeals process to provide entities with reporting obligations a formal structure in which to appeal any notice of a pending or imposed CMP. We would

expect that this proposed rule, once finalized, would comport with the appeals process as prescribed by 42 CFR 402.19 and set forth under 42 CFR part 1005. In broad terms, parties subject to CMP would receive formal written notice at the time penalty is proposed. The recipient would have the right to request a hearing with an Administrative Law Judge (ALJ) within 60 calendar days of receipt. Any party may appeal the initial decision of the ALJ to the Departmental Appeals Board (DAB) within 30 calendar days. The DAB's decision becomes binding 60 calendar days following service of the DAB's decision, absent petition for judicial review

6. Rule is Prospective

Many commenters suggested that the rule should be enforced prospectively only. We agree and would evaluate compliance based only upon files submitted by the RRE on or after the effective date of any final rule.

7. Statute of Limitations

Many commenters requested a statute of limitations on the imposition of CMPs. We agree and will apply the 5-year statute of limitations as required by 28 U.S.C. 2462. Under 28 U.S.C. 2462, we may only impose a CMP within 5 years from the date when the non-compliance was identified by CMS. An explanation and example of how this proposed statute of limitations would work for each of the three proposed types of CMPs is provided in this section of this rule.

For failure to report, the noncompliance occurs on every day of non-reporting after the required timeframe for reporting has elapsed:

If an RRE fails to report any beneficiary record as required beginning in 2023, and CMS identifies this non-compliance in 2024 but fails to take action until 2030, then no CMP would be imposed.

For responses to recovery efforts contradicting reporting, the noncompliance occurs when the response is received by CMS:

If in 2023 an RRE reported ongoing primary payment responsibility for a given beneficiary and then responded to recovery efforts 1 year later, in 2024, with an assertion that coverage for that beneficiary was actually terminated prior to the issuance of the recovery demand letter. If CMS fails to impose a CMP for this noncompliance within 5 years (no later than 2029), then no CMP would be imposed for this incident of noncompliance.

For situations where the reporter exceeds the error tolerance threshold, the noncompliance occurs at the end of the fourth consecutive reporting period over the 20 percent threshold (out of eight consecutive reporting periods):

If an RRE exceeds the error tolerance threshold in all four reporting periods of 2023 and then never exceeds the threshold again, it would normally be subject to a CMP. But if CMS fails to impose a CMP for this noncompliance within 5 years (no later than 2028), then no CMP would be imposed for this noncompliance.

We do appreciate the concerns raised by commenters and wish to reiterate that CMPs would only be imposed on a prospective basis.

8. Informal and Formal Notice

Many commenters requested that CMS explain how it will provide notice to entities regarding pending or imposed CMPs and how much information will be included.

We would expect to communicate with the entity informally before issuing formal notice regarding a CMP. Informal communications would depend upon the nature of the non-compliance. Regarding the potential imposition of CMPs on other grounds, CMS anticipates utilizing an informal (that is, prior to formal enforcement actions) written ''pre-notice'' process that would allow the RRE the opportunity to present mitigating evidence before the imposition of a CMP. Once we determine that a CMP will be imposed, we would provide formal notice to the entity in writing in accordance with 42 CFR 402.7, which would contain information on the reason for the assessment of a CMP, the amount of the CMP, and next steps for the entity, including appeal rights.

For example, we expect to continue to utilize the current messaging procedures around file errors described in the MMSEA Section 111 User Guides, which entail indicators on response files, emails, and phone calls depending upon the nature and severity of the error. RREs thus would remain informed about the performance of their quarterly file submissions. Upon the third submission out of seven consecutive reporting periods that exceeds error tolerances, the RRE would receive an ''informal notice'' that consists of a written warning letter (which requires no response, but is intended to warn the RRE that a subsequent submission that exceeds tolerances would result in potential CMP imposition). Upon the fourth submission out of eight consecutive reporting periods that exceeds error tolerances (and any additional triggering submissions), the RRE would receive another ''informal'' written notice of non-compliance indicating the nature of the non-compliance and the determination of the potential amount of the CMP, with 30 calendar days to respond with any mitigating information prior to the issuance of a notice of proposed determination in accordance with 42 CFR 402.7.

In the event that a CMP may be imposed for lack of timely reporting, CMS would issue an informal written notice of non-compliance, identifying the nature of the non-compliance and the determination of the potential amount of the CMP. The RRE would again have 30 calendar days to respond with mitigating information before the issuance of a written notice in accordance with 42 CFR 402.7.

Recovery demand letters would be revised to include information regarding the potential for CMPs should an RRE contradict its own reporting in the recovery process. If an RRE submits a dispute or redetermination request in response to the recovery process that appears to directly contradict its own reporting, an informal written notice of non-compliance identifying the nature of the non-compliance and the determination of the potential amount of the CMP would be issued to the RRE. The RRE would again have 30 calendar days to respond with mitigating information before the issuance of a written notice in accordance with 42 CFR 402.7.

9. Suspension of CMP Imposition Where Programmatic Changes Are Required

Commenters suggested that CMS consider suspending the imposition of CMPs, where changes to mandatory reporting procedure require RREs to make significant revisions to the systems used to prepare the data for reporting.

We would expect to continue to provide at least 6 months' (180 calendar days) notice regarding any changes in policy or procedure associated with section 111 of MMSEA required reporting to allow reporting entities adequate time to react. We would not assess any CMPs associated with a specific policy or procedural change for a minimum of two reporting periods following the implementation of that policy or procedural change.

10. Duplicative Reporting and CMPs

Commenters suggested that CMS should not impose CMPs in situations where required information has already been reported to another agency or entity, such as the Department of Labor, or in situations where multiple entities have obligations to report the same

information to CMS and one entity has already reported.

The reporting requirements established under sections 1862(b)(7) and (b)(8) of the Act imposed certain unique requirements on specific entities to report data to CMS for the purposes of identifying those situations where another party has primary payment responsibility. These reporting requirements were imposed under the Act, regardless of whether another agency or entity requires the same or similar data (and such data must also be reported to CMS in the manner and form specified by the Secretary). The current OMB control number assigned to this information collection effort, as required under the Paperwork Reduction Act, is 0938–1074.

11. Correct Coordination of Benefits and Recovery

Commenters suggested that CMS not impose CMPs when CMS has been able to coordinate benefits correctly or CMS has otherwise been able to recover.

The obligations to report under section 1862(b)(7) and (b)(8) of the Act are separate and distinct from any other obligation with respect to MSP. The fact that we may be able to correctly coordinate benefits and pursue recovery does not negate the obligations established under section 1862(b)(7) and (b)(8) of the Act.

II. Provisions of Proposed Regulations

We have reviewed the public comments in response to our December 11, 2013 ANPRM (78 FR 75304), and other policy considerations as discussed in section I.D. of this proposed rule. Accordingly, we are proposing specific criteria for when CMPs would be imposed and proposing specific criteria for when CMPs would not be imposed, in circumstances when a GHP or an NGHP entity fails to comply (either on its own or through a reporting agent) with MSP reporting requirements specified under section 1862(b)(7) and (b)(8) of the Act. We note that the proposed CMPs would be levied in addition to any MSP reimbursement obligations.

Further, we proposed to amend the amount of these CMPs, as set forth under 45 CFR 102.3 (Penalty adjustment and table).

A. CMP Bases and Scope

Section 402.1 describes the basis for imposition CMPs against parties who violate the provisions of the Act. We propose to add regulatory language under § 402.1(c), which would identify situations in which GHP entities and NGHP entities with RREs would be subject to CMPs under sections 1862(b)(7) and (b)(8) of the Act. To accomplish this regulatory addition, we are proposing the following regulatory revisions in § 402.1:

- Removing paragraph (c)(20).
- Redesignating paragraph (c)(21) as paragraph (c)(20).
- Redesignating paragraphs (c)(22) through (34) as paragraphs (c)(23) through (35).
- Adding new paragraphs (c)(21) and (22).

Section 402.105(b) establishes the amount of penalties assessed against parties who violate the provisions of the Act. The proposed regulation at § 402.105(b)(2) would establish the amount of penalties imposed against GHPs, and the proposed regulation at § 402.105(b)(3) would establish the amount of penalties imposed against NGHPs. The regulatory provisions proposed would amend § 402.105(b) by revising paragraph (b)(2) and adding a new paragraph (b)(3). The proposed regulatory changes would establish the amount of CMPs imposed in these situations.

In addition, we have revised the regulations at 45 CFR 102.3 to establish the updated amounts for all CMPs at issue in these and the impacted proposed regulations. The table in this section sets forth the changes described for these amounts.

B. CMP Imposition and Amounts

The proposed regulations at § 402.1(c) would identify circumstances where GHP entities and NGHP entities with RREs would be subject to CMPs for violation of sections 1862(b)(7) and (b)(8) of the Act. We may become aware of these violations through various means. Currently self-referral is the most common means by which RREs that have failed to properly register and report are identified, which we expect to continue. Following publication of the final rule, we will enhance monitoring of recovery process disputes and appeals that contradict reported data, as well as monitoring of the reported data and performance over time to identify reporting that exceeds error tolerances. The proposed regulations at § 402.105(b) would clarify how we would calculate CMP amounts for GHP and NGHP entities that have reporting obligations under sections 1862(b)(7) and (b)(8) of the Act. Furthermore, the proposed § 402.1(c) would identify situations where GHP and NGHP RREs would not be subject to CMPs for violation of section 1862(b)(7) and (b)(8) of the Act.

Under section 1862(b)(7) of the Act, a GHP RRE shall be subject to a CMP of $1,000 as adjusted annually under 45 CFR part 102 (currently $1,569 as of January 17, 2020; please see 85 FR 2869) for each calendar day of noncompliance for each individual for which the required information should have been submitted. Under section 1862(b)(8) of the Act, an NGHP RRE may be subject to a CMP of up to $1,000 (as adjusted annually under 45 CFR part 102) for each calendar day of noncompliance for each individual for which the required information should have been submitted. These CMPs would be in addition to any other penalties prescribed by law, and in addition to any MSP claim under section 1862(b) of the Act with respect to an individual.

1. Imposition of a CMP

We would impose a CMP in the following situations:

- If an RRE fails to report any GHP beneficiary record within the required timeframe (no more than 1 calendar year after GHP coverage effective date or the Medicare beneficiary's entitlement date, whichever is later). The penalty would be calculated on a daily basis, based on the actual number of individual beneficiaries' records that the entity submitted untimely (that is, beyond the required timeframe after the GHP MSP effective date). The penalty would be $1,000 (as adjusted annually under 45 CFR part 102) for each calendar day of noncompliance for each individual for which the required information should have been submitted, as counted from the day after the last day of the RRE's assigned reporting window where the information should have been submitted through the day that CMS received the information, up to a maximum penalty of $365,000 (as adjusted annually under 45 CFR part 102, currently $572,685) per individual per year.
- If an RRE fails to report any NGHP beneficiary record within the required timeframe (no more than 1 year of the date of the settlement, judgment, award, or other payment (also referred to as the Total Payment Obligation to Claimant (TPOC)). The penalty would be calculated on a daily basis, based on the actual number of individual beneficiaries' records that the entity submitted untimely (that is, in excess of the required timeframe after the TPOC date). The penalty would be up to $1,000 (as adjusted annually under 45 CFR part 102) for each calendar day of noncompliance for each individual for which the required information should have been submitted, as counted from the day after the last day of the RRE's assigned reporting window where the information should have been submitted through the day that CMS received the

information, up to a maximum penalty of $365,000 (as adjusted annually under 45 CFR part 102) per individual per year.

• If a GHP's or NGHP's response to CMS recovery efforts contradicts the entity's section 111 of MMSEA reporting. For example, if an RRE reported and repeatedly affirmed ongoing primary payment responsibility for a given beneficiary, then responded to recovery efforts with the assertion that coverage for that beneficiary actually terminated 2 years prior to the issuance of the recovery demand letter. The penalty would be calculated based on the number of calendar days that the entity failed to appropriately report updates to beneficiary records, as required for accurate and timely reporting under section 111 of MMSEA. For a GHP, the penalty would be $1,000 (as adjusted annually under 45 CFR part 102) for each calendar day of noncompliance for each individual for which the required information should have been submitted. For an NGHP, the penalty would be up to $1,000 (as adjusted annually under 45 CFR part 102) per calendar day of noncompliance for each individual, for a maximum annual penalty of $365,000 (as adjusted annually under 45 CFR part 102) for each individual for which the required information should have been submitted.

• If a GHP or NGHP entity has reported, and exceeds any error tolerance(s) threshold established by the Secretary in any 4 out of 8 consecutive reporting periods. We propose that the initial and maximum error tolerance threshold would be 20 percent (representing errors that prevent 20 percent or more of the beneficiary records from being processed), with any reduction in that tolerance to be published for notice and comment in advance of implementation. We intend for this tolerance to be applied as an absolute percentage of the records submitted in a given reporting cycle; we welcome feedback on this proposed methodology and threshold. The errors that would be used to determine whether the error tolerance is met must also be defined in advance of implementation of the final rule; we are only considering those significant errors which prevent a file or individual beneficiary record from processing. These errors are defined in the Section 111 User Guides, but we welcome the public's feedback. We would maintain the current notification process in place where RREs receive notice via response file and direct outreach (email and, in more serious cases, telephone call) when there are errors with their file submissions.

Although the Act indicates that CMPs are calculated based on the number of days of RRE noncompliance, RREs do not report on a daily basis and so non-conformance in this situation cannot be defined on a daily basis. Therefore under this proposed rule, an RRE is considered to be out of compliance for the entire reporting period when the RRE exceeds the error tolerance threshold. A reporting period is defined as one quarter (defined as 90 calendar days for the purposes of standardizing quarters). For a GHP entity, the penalty would be imposed if the GHP entity was determined to have exceeded the error tolerances(s) in the entity's fourth above-tolerance submission out of any eight consecutive reporting periods. The penalty would be $1,000 (as adjusted annually under 45 CFR part 102) for each calendar day of noncompliance for each individual for which the required information should have been submitted. An RRE is considered to be out of compliance for the entire reporting period when the error tolerance is exceeded; as previously noted, a reporting period is currently defined as one quarter (standardized to 90 calendar days). Therefore, the penalty for a non-compliant GHP would be $90,000 (as adjusted, currently $141,210) for each individual for which the required information should have been submitted, per reporting period where a CMP may be imposed.

For an NGHP entity, a CMP would be imposed on a tiered approach if the NGHP entity exceeded the error tolerance(s) in the entity's fourth above-tolerance submission. As with GHP entities, an NGHP entity is considered to be out of compliance for the entire reporting period when the error tolerance is exceeded; a reporting period is defined as one quarter, standardized to 90 calendar days. For the first level of this penalty (reflecting the fourth submission exceeding error tolerances in any of the previous eight consecutive reporting periods), we would impose a penalty of one quarter, or 25 percent, of the maximum penalty per individual record per calendar day of non-compliance (this maximum penalty is currently defined as $1,000, as adjusted annually under 45 CFR part 102) after the required date of submission (last calendar day of the NGHP's reporting period), based upon the number of beneficiaries whose records exceeded any error tolerance(s) established by the Secretary. In effect, $250 (as adjusted, currently $392) per calendar day, over the 90 calendar days of non-compliance for the full reporting period, per individual record. If the NGHP entity fails to comply again in the next consecutive reporting period, the amount of the penalty would increase to one half, or 50 percent, of the maximum penalty (currently defined as $1000, as adjusted annually under 45 CFR part 102) per beneficiary per calendar day of non-compliance. In effect, $500 (as adjusted, currently $785) per calendar day, over the 90 calendar days of non-compliance for the full reporting period, per individual record. If the NGHP entity fails to comply again in the next consecutive reporting period, the amount would increase again to three-quarters, or 75 percent, of the maximum penalty (currently defined as $1,000, as adjusted annually under 45 CFR part 102), and so on, up to the maximum penalty of $1,000 (as adjusted annually under 45 CFR part 102) per beneficiary per calendar day of non-compliance (in effect, $90,000 as adjusted, over the 90 calendar days of non-compliance for the full reporting period, per individual record). However, the potential penalty amount for the next penalty-eligible file would be reduced by one quarter (25 percent) of the maximum penalty of $1,000 (as adjusted annually under 45 CFR part 102) per individual record per calendar day of non-compliance for each immediately consecutive subsequent quarter of compliance where an NGHP entity reports after the assessment of a penalty and the entity remains below any error tolerances. Such reductions may accumulate for each subsequent reporting period where the entity remains below the error tolerance until the entity is once again at the minimum penalty of one quarter, or 25 percent, of the maximum penalty per individual record per calendar day of non-compliance.

The following chart depicts how the concept of ''any 4 out of the most recent 8 consecutive reporting periods'' would work. CMP amounts are used for illustration purposes only; all amounts should be assumed to be adjusted annually.

Example	Year 1				Year 2				Year 3				CMP Imposed
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
1	E	E	G	E	G	G	G	E	G	G	E	G	Q4 of Year 2.
2	E	E	G	G	G	G	E	G	G	G	E	E	No.
3	*	*	*	*	E	G	E	G	G	G	G	E	No.
4	*	*	*	E	E	G	G	E	G	G	E	E	Q3 and Q4 of Year 3.
5	*	E	G	E	G	E	G	E	G	E	G	G	Q4 of Year 2 and Q2 of Year 3.

Key: * = No File; E = Error Tolerance Exceeded; G = Good File.

The following explanations correlate to the examples depicted in this chart.

Example 1. CMP Imposed: Error tolerances exceeded in 4 out of 8 quarters as of year 2, quarter 4. As of year 3, quarter 3, there are only three out of eight quarters where submissions exceeded error tolerances, so no additional CMP would be imposed.

Example 2. No CMP Imposed: In no 8 sequential quarters were error tolerances exceeded 4 or more times.

Example 3. No CMP Imposed: In no 8 sequential quarters were error tolerances exceeded 4 or more times.

Example 4. CMP Imposed: Error tolerances were exceeded in 4 out of 8 quarters as of year 3, quarter 3. The subsequent submission (year 3, quarter 4) also exceeded error tolerances. According to the assessments proposed for GHP reporting entities, a GHP RRE would be assessed a CMP of $1,000 per calendar day for each individual for whom information should have been submitted. According to the tiered approach proposed for NGHP reporting entities discussed later, an NGHP RRE would be assessed a CMP of $250 per calendar day per for quarter 3 and $500 per beneficiary above the tolerance per calendar day for quarter 4.

Example 5. CMP Imposed: Error tolerances were exceeded in 4 out of 7 quarters by year 2, quarter 4. According to the assessments proposed for GHP reporting entities, a GHP RRE would be assessed a CMP of $1,000 per calendar day for each individual for whom information should have been submitted. According to the tiered approach proposed for NGHP reporting entities discussed later, an NGHP RRE would be assessed a CMP of $250 per calendar day per individual for whom information should have been submitted. Error tolerances were again exceeded in year 3, quarter 2. Because error tolerances were not exceeded in year 3, quarter 1, an NGHP RRE would only be assessed a CMP of $250 per calendar day per individual for whom information should have been submitted for year 3, quarter 2 instead of $500.

The following examples demonstrate how the concept of exceeding error tolerances in ''any 4 out of 8 consecutive reporting periods'' would work:

Example 1: The RRE, ABC Insurer, submitted a file for each quarter in Year 1 of its required submissions. For Year 1, quarters 1 and 2, ABC Insurer submitted files where the file submissions entirely failed processing (100 percent error rate), and thus the quarterly submissions exceeded the error rate tolerance. In quarter 3 of Year 1, ABC Insurer submitted a file with no serious errors that prevented the files from being processed. However, severe file errors again occurred in quarter 4 and 25 percent of its records failed. These errors were corrected by the RRE for the first quarter of Year 2. ABC Insurer continued to submit error-free files for quarter 2 and quarter 3 of Year 2. However, in quarter 4 of Year 2, 50 percent of the submitted records failed. CMS would impose a CMP because the error tolerances exceeded four out of the eight quarterly reporting periods as of quarter 4 of Year 2.

Example 2: In the first two quarters of Year 1, Acme Insurance submitted files with errors that prevented 30 percent of the records from processing (exceeding error tolerances for quarter 1 and quarter 2). The file submissions for the last two quarters of Year 1 and quarters 1 through 3 of Year 2 did not have any significant errors and did not exceed tolerances. However, quarter 4 of Year 2 saw a recurrence of serious errors and Acme Insurance again exceeded the error tolerance with 25 percent of its records failing to process. Quarters 1 and 2 of Year 3 did not exceed tolerances, but the third and fourth quarters of Year 3 again saw Acme Insurance exceed the error tolerance with 30 percent and 20 percent of its records failing to process, respectively. CMS would not impose a CMP as in no continuous eight reporting periods did Acme Insurance exceed error tolerance four or more times.

We are proposing a maximum 20 percent per file submission error tolerance. Any future modification to this error tolerance threshold will be subject to notice and comment. We would not consider submission errors that fall below this tolerance in determining the imposition of a potential CMP; we would continue to provide the response file that allows submitters to be aware of their performance. We have evaluated the historical error rates from RRE submissions and have determined that the vast majority of submitters are able to meet or exceed this initial minimum acceptable performance level. The 20 percent per file tolerance for errors would only include those errors and condition flags that are within the entities' direct control and cause CMS to be unable to process the individual beneficiary records or entire file submissions. The errors that would be used to determine whether the error tolerance is met shall also be defined a minimum of 6 months in advance of imposition of any CMP (after publication of the final rule) in the reporting User Guides and will be subject to notice and comment. We would only consider those significant errors which prevent a file or individual beneficiary record from processing, such as failure to provide an individual's last name or valid date of birth, or failure to provide a matching Tax Identification Number. Less serious errors, such as internal CMS processing errors, will continue to be noted on the response files, but will not be considered in determining compliance. We currently interact with RREs to inform them of errors with file submissions, between response files to email notifications to, in more severe situations, direct telephone outreach. Following publication of the final rule, we would implement a monitoring system but would continue to review submissions each reporting period to determine whether the entity has continued to exceed error tolerance(s) and preserve the notification apparatus currently in place. GHP and NGHP entities will continue to have penalties assessed for each reporting period, until the entity submits a file that does not exceed any error tolerance(s).

2. No CMP Imposed

We would not impose a CMP in the following situations, where all of the applicable conditions are met:

• If a RRE reports any GHP beneficiary record that is reported on a quarterly submission timeframe within the required timeframe (not to exceed 1 year after the GHP effective date), or any NGHP beneficiary record that is submitted within the required timeframe (not to exceed 1 year after the TPOC date).

• If an RRE complies with any TPOC reporting thresholds or any other reporting exclusions published in CMS's MMSEA Section 111 User Guides or otherwise granted by CMS. Note that these thresholds are not defined in the regulatory text as TPOC reporting thresholds are currently subject to change on an annual basis per 42 U.S.C. 1395(y)(b)(9)(i). CMS also elects to impose operational thresholds for reporting, such as the current $5,000 threshold for Health Reimbursement Arrangements.

• If a GHP entity or NGHP entity does not exceed any error tolerance(s) in any four out of eight consecutive reporting periods.

• If an NGHP entity fails to report required information because the NGHP entity was unable to obtain information necessary for reporting from the reportable individual, including an individual's last name, first name, date of birth, gender, MBI, or SSN (or the last 5 digits of the SSN), and the responsible applicable plan has made and maintained records of its good faith effort to obtain this information by taking *all* of the following steps:

++ The NGHP has communicated the need for this information to the individual and his or her attorney or other representative and requested the information from the individual and his or her attorney or other representative at least twice by mail and at least once by phone or other means of contact such as electronic mail in the absence of a response to the mailings.

++ The NGHP certifies that it has not received a response in writing, or has received a response in writing that the individual will not provide his or her MBI or SSN (or last 5 digits of his or her SSN).

++ The NGHP has documented its records to reflect its efforts to obtain the MBI or SSN (or the last 5 digits of the SSN) and the reason for the failure to collect this information.

The NGHP entity should maintain records of these good faith efforts (such as dates and types of communications with the individual) in order to be produced as mitigating evidence should CMS contemplate the imposition of a CMP. Such records must be maintained for a period of 5 years. The current OMB control number assigned to this information collection effort, as required under the Paperwork Reduction Act, is 0938–1074.

We solicit comments on our proposed approaches to imposing and not imposing CMPs, including our proposed methods of calculating CMP amounts, and our proposed error tolerance rates. Our proposed approach to imposing CMPs was developed to give entities meaningful opportunities to resolve most reporting issues, without the immediate risk that a CMP would be imposed.

III. Collection of Information Requirements

This document does not impose any new information collection and recordkeeping requirements that have not already been reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Responses to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the ''DATES'' section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the 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 (CRA) (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). A detailed regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Estimating the economic effects of this rule presents a significant challenge under current circumstances. At this point in time, the reporting program has not yet reached a level of maturity where we have definitively identified any additional RREs that have failed to register and report as required. We have purposely selected an error tolerance threshold (20 percent) that is achievable for all current RREs based on recent performance, and thus would not impose any CMPs based on current performance. However, we do not yet have eight consecutive reporting periods of data, and, as such, we are not able to currently model the potential imposition of CMPs on this basis at this time. We also do not have the systems in place at this time to monitor when entities contradict their reported data in response to CMS MSP recovery efforts. At this point in time, we do not expect to collect CMPs totaling $100 million or more in any given year, nor do we expect this rule to have any other economic effects that meet or exceed that threshold. Therefore, this rule is not considered a major rule under the CRA. We note that we are currently implementing monitoring systems that will allow us to better model future reporting violations and CMP imposition. Therefore, when we are ready to develop the final rule we expect to have available a significantly increased array of relevant data. As a result, we commit to providing a detailed analysis of the costs and benefits of this rule at that time. We also invite feedback from the public that would assist us in determining the quantifiable costs and benefits of this proposed rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $35.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We consider a rule to have a significant impact on a substantial number of small entities if it has at least a 3-percent impact of revenue on at least 5 percent of small entities. Affected entities with reporting responsibilities have been required to comply with sections 1862(b)(7) and (b)(8) of the Act since these provisions were added to the Act in 2007. This proposed rule is intended to define how CMPs would be

imposed as a consequence of non-compliance with these statutory obligations, and thus does not present any additional burden beyond the review of the rule. As discussed later in this section, the total cost impact of reviewing this rule by all 20,855 currently registered RREs, regardless of size, is estimated to be $6,842,437, or $328 per entity. This falls below the standard definition of ''significance'' of 3 or more of small entity revenue. As a result, we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA 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 for the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. This proposed rule has no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 It has been determined that this proposed rule is not a ''significant regulatory action'' and thus does not trigger the previously discussed requirements of Executive Order 13771.

We used the current number of GHP RREs (1,039) and NGHP RREs (19,816) to determine the total number of impacted entities (20,855). We recognize that this is a slight overestimate, as a single corporate parent may have multiple associated RREs. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

Using the May 2018 wage information from the U.S. Department of Labor Bureau of Labor Statistics for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $109.36 per hour, based on doubling the mean hourly wage of $54.68 to include overhead and fringe benefits (see *https://www.bls.gov/oes/current/oes119111.htm*). We assume that one individual associated with each of the 20,855 impacted entities will read the rule. Assuming an average reading speed, we estimate that it would take approximately 3 hours for the staff to review this proposed rule. For each entity that reviews the rule, the estimated cost is $328.08 (3 hours × $109.36). Therefore, we estimate that the total cost of reviewing this proposed rule is $6,842,437 ($328.08 × 20,855).

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 402

Assessments, Civil money penalties, Exclusions.

45 CFR Part 102

Administrative practice and procedure, Penalties.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 402—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS

■ 1. The authority citation for part 402 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 402.1 is amended—

■ a. In paragraph (c) introductory text by removing the reference ''(c)(34) of this section'' and adding in its place the reference ''(c)(35) of this section'';

■ b. By removing paragraph (c)(20);

■ c. By redesignating paragraph (c)(21) as paragraph (c)(20);

■ d. By redesignating paragraphs (c)(22) through (34) as paragraphs (c)(23) through (35); and

■ e. By adding new paragraphs (c)(21) and (22).

The additions read as follows:

§ 402.1 Basis and scope.

* * * * *

(c) * * *

(21) Section 1862(b)(7)(B)—Except for the situation described in paragraphs (c)(21)(iv)(A) and (B) of this section, any entity that has a reporting obligation under section 1862(b)(7) of the Act (''reporting entity'') reports, but fails to comply with the reporting instructions in the following situations:

(i) Fails to report any beneficiary record within 1 year from the group health plan (GHP) coverage effective date or the Medicare beneficiary's entitlement date.

(ii) Contradicts its reporting under section 1862(b)(7) of the Act in response to CMS recovery efforts.

(iii) Has reported and exceeds any error tolerance(s) threshold established by the Secretary in any 4 out of 8 consecutive reporting periods.

(iv) A civil money penalty (CMP) is not imposed if—

(A) It is associated with a specific policy or procedural change is not imposed for a minimum of two reporting periods following the implementation of that policy or procedural change; or

(B) The entity complies with any reporting thresholds or any other reporting exclusions.

(22) Section 1862(b)(8)(E)—An applicable plan has a reporting obligation under section 1862(b)(8) of the Act (''applicable plan''), but fails to comply with the reporting instructions in the following situations:

(i) Except for the situations described in paragraphs (c)(22)(iv)(A) through (C) of this section, fails to report any beneficiary record within 1 year from the date of the settlement, judgment, award, or other payment.

(ii) Contradicts its reporting under section 1862(b)(8) of the Act in response to CMS recovery efforts.

(iii) Has reported, and exceeds any error tolerance(s) threshold established by the Secretary (not to exceed 20 percent) in any 4 out of 8 (or less) consecutive reporting periods.

(iv) A CMP is not imposed in the following situations:

(A) If a non-group health plan (NGHP) applicable plan fails to report required information as a result of the applicable plan's inability to obtain an individual's last name, first name, date of birth, gender, Medicare Beneficiary Identifier (MBI), Social Security Number (SSN), or the last 5 digits of the SSN, and the applicable plan has made a good faith effort to obtain this information by meeting all of the following:

(*1*) Communicating the need for this information to the individual and his or her attorney or other representative.

(*2*) Requesting the information from the individual and his or her attorney or other representative at least twice by mail and at least once by phone or other means of contact.

(*3*) Has not received a response or has received a response in writing that the individual refuses to provide his or her MBI or SSN or a truncated form of the MBI or SSN.

(*4*) Has documented its efforts to obtain the MBI or SSN (or the last 5 digits of the SSN).

(B) A CMP is not imposed if an NGHP applicable plan complies with any reporting thresholds or any other reporting exclusions.

(C) A CMP associated with a specific policy or procedural change is not imposed for a minimum of two reporting periods following the implementation of that policy or procedural change.

* * * * *

■ 3. Section 402.105 is amended by revising paragraphs (b)(2) and adding paragraph (b)(3) to read as follows:

§ 402.105 Amount of penalty.

* * * * *

(b) * * *

(2) For entities with reporting obligations under section 1862(b)(7) of the Act (''reporting entity'') as follows:

(i) A reporting entity fails to report any beneficiary record within the specified period from the latter of the GHP coverage effective date or the Medicare beneficiary's entitlement date. The penalty is—

(A) Calculated on a daily basis, based on the actual number of beneficiary records that the entity submitted more than 1 year after the GHP Medicare Secondary Payer (MSP) effective date; and

(B) $1,000 as adjusted annually under 45 CFR part 102 for each calendar day of noncompliance for each individual for which the required information should have been submitted, up to a maximum penalty of $365,000 as adjusted annually under 45 CFR part 102 per individual per year.

(ii) A reporting entity's response to CMS recovery efforts contradicts the entity's reporting under section 1862(b)(7) of the Act. The penalty is—

(A) Calculated based on the number of calendar days that the entity failed to appropriately report updates to beneficiary records, as required for accurate and timely reporting; and

(B) $1,000 as adjusted annually under 45 CFR part 102 for each calendar day of noncompliance for each individual for which the required information should have been submitted.

(iii) A reporting entity has reported, and exceeds any error tolerance(s) threshold established by the Secretary (not to exceed 20 percent) in any 4 out of 8 (or less) consecutive reporting periods. The penalty is—

(A) Based upon the number of beneficiary records on the fourth submission that exceed any such error tolerance(s); and

(B) $1,000 as adjusted annually under 45 CFR part 102 for each calendar day of noncompliance for each individual for which the required information should have been submitted.

(3) For entities with reporting obligations under section 1862(b)(8) (''applicable plan'') of the Act as follows:

(i) An applicable plan fails to report any NGHP beneficiary record within the specified period from the date of the settlement, judgment, award, or other payment. The penalty is—

(A) Calculated on a daily basis, based on the actual number of beneficiary records that the entity submitted more than 1 year after the Total Payment Obligation to Claimant (TPOC) date; and

(B) Up to $1,000 as adjusted annually under 45 CFR part 102 for each calendar day of noncompliance for each individual for which the required information should have been submitted, up to a maximum penalty of $365,000 as adjusted annually under 45 CFR part 102 per individual per year.

(ii) An applicable plan's response to CMS recovery efforts contradicts the entity's reporting under section 1862(b)(8) of the Act. The penalty is—

(A) Calculated based on the number of calendar days that the entity failed to appropriately report updates to beneficiary records, as required for accurate and timely reporting; and

(B) Up to $1,000 as adjusted annually under 45 CFR part 102 per calendar day of noncompliance, for a maximum penalty of $365,000 as adjusted annually under 45 CFR part 102.

(iii) An applicable plan has reported, and exceeds any error tolerance(s) threshold established by the Secretary (not to exceed 20 percent) in any 4 out of 8 consecutive reporting periods. The penalty is calculated using the following tiered approach, based on the number of calendar days that the applicable plan exceeded the error tolerance(s) in the entity's fourth above-tolerance submission.

(A) *Initial penalty amount.* For the first penalty, CMS imposes a penalty of one-quarter (25 percent) of the maximum penalty per beneficiary per calendar day of non-compliance after the required date of submission (last calendar day of the applicable plan's reporting period), based upon the number of beneficiaries whose records exceeded any error tolerance(s) established by the Secretary.

(B) *Subsequent penalty amounts.* For the second and subsequent penalties, CMS increases the penalty specified in paragraph (b)(3)(iii)(A) of this section in increments of one-quarter (25 percent) of the maximum penalty for applicable plans that fail to comply in consecutive reporting periods to a maximum of $1,000 as adjusted annually under 45 CFR part 102 per beneficiary per calendar day of non-compliance.

(C) *Reduction in penalty amount.* If the applicable plan reports after the assessment of a penalty and the entity remains below any error tolerances, the penalty amount for the next penalty eligible file is reduced by increments of one-quarter (25 percent) of the maximum penalty per beneficiary per calendar day of non-compliance per consecutive subsequent quarter of compliance, to the minimum penalty of one-quarter (25 percent) of the maximum penalty per beneficiary per calendar day of non-compliance.

* * * * *

For the reasons specified in the preamble, the Department of Health and Human Services proposes to amend 45 CFR part 102 as specified below:

PART 102—ADJUSTMENT OF CIVIL MONETARY PENALTIES FOR INFLATION

■ 4. The authority for part 102 continues to read as follows:

Authority: Public Law 101–410, Sec. 701 of Public Law 114–74, 31 U.S.C. 3801–3812.

■ 5. Section 102.3 is amended in the table by:

■ a. Revising the entries ''1395m(k)(6),'' ''1395m(l)(6),'' ''1395y(b)(6)(B),'' and ''1395y(b)(7)(B)(i);''

■ b. Adding an entry for ''1395y(b)(8)(E)(i)'' in alphanumeric order; and

■ c. Revising the entries for ''1395pp(h),'' ''1395ss(a)(2),'' ''1395ss(p)(8),'' ''1395ss(p)(9)(C),'' ''1395ss(q)(5)(C),'' ''1395ss(r)(6)(A),'' ''1395ss(s)(4),'' and ''1395ss(t)(2).''

The revisions and addition read as follows:

§ 102.3 Penalty adjustment and table.

* * * * *

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS

[January 17, 2020]

	CFR [1]	HHS agency	Description [2]	Date of last statutorily established penalty figure [3]	2019 maximum adjusted penalty ($)	2020 maximum adjusted penalty ($) [4]
*	*	*	* *	*	*	
42 U.S.C:						
*	*	*	* *	*	*	
1395m(k)(6) [5]	42 CFR 402.1(c)(32), 402.105(d)(3).	CMS	Penalty for any person or entity who knowingly and willfully bills or collects for any outpatient therapy services or comprehensive outpatient rehabilitation services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(k)(6) and 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2019	15,975	16,257
1395m(l)(6) [5]	42 CFR 402.1(c)(33), 402.105(d)(4).	CMS	Penalty for any supplier of ambulance services who knowingly and willfully fills or collects for any services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(b)(18)(B), which is assessed according to 1320a–7a(a)).	2019	15,15,975	16,257
*	*	*	* *	*	*	
1395y(b)(6)(B)	42 CFR 402.1(c)(20), 402.105(a).	CMS	Penalty for any entity that knowingly, willfully, and repeatedly fails to complete a claim form relating to the availability of other health benefits in accordance with statute or provides inaccurate information relating to such on the claim form.	2019	3,383	3,443
1395y(b)(7)(B)(i)	42 CFR 402.1(c)(21), 402.105(a).	CMS	Penalty for any entity serving as insurer, third party administrator, or fiduciary for a group health plan that fails to provide information that identifies situations where the group health plan is or was a primary plan to Medicare to the HHS Secretary.	2019	1,211	1,232
*	*	*	* *	*	*	
1395y(b)(8)(E)(i)	42 CFR 402.1(c)(22), 402.105(a)(E).	CMS	Penalty for any entity serving as insurer, third party administrator, or fiduciary for a non-group health plan that fails to provide information that identifies situations where the group health plan is or was a primary plan to Medicare to the HHS Secretary.	2019	1,211	1,232
*	*	*	* *	*	*	
1395pp(h) [5]	42 CFR 402.1(c)(24), 402.105(d)(2)(xv).	CMS	Penalty for any durable medical equipment supplier, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries under certain conditions. (42 U.S.C. 1395(m)(18) sanctions apply here in the same manner, which is under 1395u(j)(2) and 1320a–7a(a)).	2019	15,975	16,257
1395ss(a)(2)	42 CFR 402.1(c)(25), 405.105(f)(1).	CMS	Penalty for any person that issues a Medicare supplemental policy that has not been approved by the State regulatory program or does not meet Federal standards after a statutorily defined effective date.	2019	54,832	55,799
*	*	*	* *	*	*	
1395ss(p)(8)	42 CFR 402.1(c)(26), 402.105(e).	CMS	Penalty for any person that sells or issues Medicare supplemental polices after a given date that fail to conform to the NAIC or Federal standards established by statute.	2019	28,413	28,914
	42 CFR 402.1(c)(26), 405.105(f)(2).	CMS	Penalty for any person that sells or issues Medicare supplemental polices after a given date that fail to conform to the NAIC or Federal standards established by statute.	2019	47,357	48,192
1395ss(p)(9)(C)	42 CFR 402.1(c)(27), 402.105(e).	CMS	Penalty for any person that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits.	2019	28,413	28,914

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued

[January 17, 2020]

	CFR [1]	HHS agency	Description [2]	Date of last statutorily established penalty figure [3]	2019 maximum adjusted penalty ($)	2020 maximum adjusted penalty ($) [4]
	42 CFR 402.1(c)(27), 405.105(f)(3), (4).		Penalty for any person that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits.	2019	47,357	48,192
1395ss(q)(5)(C)	42 CFR 402.1(c)(28), 405.105(f)(5).	CMS	Penalty for any person that fails to suspend the policy of a policyholder made eligible for medical assistance or automatically reinstates the policy of a policyholder who has lost eligibility for medical assistance, under certain circumstances.	2019	47,357	48,192
1395ss(r)(6)(A)	42 CFR 402.1(c)(29), 405.105(f)(6).	CMS	Penalty for any person that fails to provide refunds or credits as required by section 1882(r)(1)(B).	2019	47,357	48,192
1395ss(s)(4)	42 CFR 402.1(c)(30), 405.105(c).	CMS	Penalty for any issuer of a Medicare supplemental policy that does not waive listed time periods if they were already satisfied under a proceeding Medicare supplemental policy, or denies a policy, or conditions the issuances or effectiveness of the policy, or discriminates in the pricing of the policy base on health status or other specified criteria.	2019	20,104	20,459
1395ss(t)(2)	42 CFR 402.1(c)(31), 405.105(f)(7).	CMS	Penalty for any issuer of a Medicare supplemental policy that fails to fulfill listed responsibilities.	2019	47,357	48,192
*	*	*	*	*	*	*

[1] Some HHS components have not promulgated regulations regarding their civil monetary penalty-specific statutory authorities.
[2] The description is not intended to be a comprehensive explanation of the underlying violation; the statute and corresponding regulation, if applicable, should be consulted.
[3] Statutory or Inflation Act Adjustment.
[4] The cost of living multiplier for 2018, based on the CPI–U for the month of October 2017, not seasonally adjusted, is 1.02041, as indicated in OMB Memorandum M–18–03, ''Implementation of Penalty Inflation Adjustments for 2018, Pursuant to the Federal Civil Penalties Adjustment Act Improvements Act of 2015'' (December 15, 2017).
[5] The cost of living multiplier for 2020, based on the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October 2019, not seasonally adjusted, is 1.01764, as indicated in OMB Memorandum M–20–05, ''Implementation of Penalty Inflation Adjustments for 2019, Pursuant to the Federal Civil Penalties Adjustment Act Improvements Act of 2015'' (December 16, 2019).

Dated: August 12, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 12, 2019.

Alex Azar,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–03069 Filed 2–13–20; 11:15 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 54

[WC Docket Nos. 18–143 and 10–90; Report No. 3142; FRS 16493]

Petition for Reconsideration of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petition for Reconsideration.

SUMMARY: A Petition for Reconsideration (Petition) has been filed in the Commission's rulemaking proceeding by L. Charles Keller, on behalf of Virgin Islands Telephone Corporation dba Viya.

DATES: Oppositions to the Petition must be filed on or before March 4, 2020. Replies to an opposition must be filed on or before March 16, 2020.

ADDRESSES: Federal Communications Commission, 445 12th Street SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Alexander Minard, email: *Alexander.Minard@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, Report No. 3142, released February 6, 2020. The full text of the Petition is available for viewing and copying at the FCC Reference Information Center, 445 12th Street SW, Room CY–A257, Washington, DC 20554. It also may be accessed online via the Commission's Electronic Comment Filing System at: *http://apps.fcc.gov/ecfs/.* The Commission will not send a Congressional Review Act (CRA) submission to Congress or the Government Accountability Office pursuant to the CRA, 5 U.S.C. 801(a)(1)(A) because no rules are being adopted by the Commission.

Subject: The Uniendo a Puerto Rico Fund and the Connect America USVI Fund, Connect America Fund; DA 19–1300, released by the Commission on December 19, 2019, in WC Docket Nos. 18–143, 10–90. This document is being published pursuant to 47 CFR 1.429(e). *See also* 47 CFR 1.4(b)(1) and 1.429(f), (g).

Number of Petitions Filed: 1.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020–03148 Filed 2–14–20; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register

Vol. 85, No. 32

Tuesday, February 18, 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

Submission for OMB Review; Comment Request

February 11, 2020.

The Department of Agriculture will submit the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. Comments are requested regarding: 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; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, Washington, DC; New Executive Office Building, 725 17th Street NW, Washington, DC 20503. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602.

Comments regarding these information collections are best assured of having their full effect if received by March 19, 2020. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

National Agricultural Statistics Service

Title: Poultry Litter Nutrient Distribution Producer Survey.

OMB Control Number: 0535–0264.

Summary of Collection: The primary objectives of the National Agricultural Statistics Service (NASS) are to prepare and issue official State and national estimates of crop and livestock production, disposition and prices, economic statistics, and environmental statistics related to agriculture and to conduct the Census of Agriculture and its follow-on surveys. NASS will conduct a survey of select agricultural operations in Delaware, Maryland, Pennsylvania, and Virginia. Each selected farmer or rancher will be asked to provide data on (1) Basic crop and tillage practices in 2019, (2) Preferred sources of nutrients and actual sources of nutrients used, (3) Where the operator gets information and recommendations on nutrients, and (4) Farmer perception between poultry litter co-products and other sources of nutrients. General authority for these data collection activities is granted under U.S.C. Title 7, Section 2204.

Need and Use of the Information: A comprehensive evaluation of farmer preferences for using fresh poultry litter or poultry litter ash co-products has not been previously conducted in the Chesapeake Bay area.

Data may be used for market development, policy, and/or budgeting for cost-share/poultry transport programs. Stakeholders would be farmers (poultry growers and crop producers), policy makers, technology vendors, fertilizer manufacturers, and manure brokers/haulers.

Information from the survey could be used by commercial fertilizer dealers, poultry growers, technology vendors, or state agencies to make investment decisions regarding fresh poultry litter and poultry litter ash co-products. For example, policy makers could base changes to the state cost share program for manure transport on the results, or a fertilizer company/technology vendor could invest in a new fertilizer product based on the results.

The survey will also complement on-going efforts in Chesapeake Bay states to achieve water quality goals via promoting on-farm and regional phosphorus balance. Several states (Maryland and Delaware for example) offer funding to transport poultry litter from farms where it is produced to fields where it is needed. Despite cost share incentives to use poultry litter, many farmers choose not to use poultry litter. This survey will identify barriers to expanded use of poultry litter on farms in the region.

Description of Respondents: A sample of all active agricultural operations in Delaware, Maryland, Pennsylvania, and Virginia that produce:

- 200 or more acres of row crops (corn, soybeans, wheat, peanuts, cotton),
- 25 or more acres of specialty crops (vegetables, fruit, flowers), and/or
- at least $10,000 of floriculture sales.

Number of Respondents: 1,000.

Frequency of Responses: Reporting: Once a year.

Total Burden Hours: 483.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2020–03067 Filed 2–14–20; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

February 12, 2020.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding 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; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of

information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by March 19, 2020 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food Safety and Inspection Service

Title: Specified Risk Materials.

OMB Control Number: 0583–0129.

Summary of Collection: The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*). The statutes mandate that FSIS protect the public by ensuring that meat products are safe, wholesome, not adulterated, and properly labeled and packaged. FSIS requires that official establishments that slaughter cattle and or process carcasses or parts of cattle develop written procedures for the removal, segregation, and disposition of specified risk materials (SRMs). FSIS requires that establishments maintain daily records sufficient to document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs, and any corrective actions taken to ensure that such procedures are effective.

Need and Use of the Information: FSIS will collect information from establishments to ensure meat and meat products distributed in commerce for use as human food do not contain SMRs.

Description of Respondents: Business or other for-profit.

Number of Respondents: 3,512.

Frequency of Responses: Recordkeeping; Reporting: On occasion.

Total Burden Hours: 123,916.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2020–03127 Filed 2–14–20; 8:45 am]

BILLING CODE 3410–DM–P

FOREIGN AGRICULTURAL SERVICE

Notice of a Request for Revision of a Currently Approved Information Collection

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act, this notice announces the Foreign Agricultural Service's intention to request a revision for a currently approved information collection relating to the issuance of certificates of quota eligibility (CQEs) required to enter sugar and sugar-containing products under tariff-rate quotas (TRQs) into the United States.

DATES: Comments on this notice must be received by no later than April 20, 2020 to be assured of consideration.

ADDRESSES: You may send comments, identified by the OMB Control number 0551–0014, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for sending comments.
- *Email: William.Janis@usda.gov.* Include OMB Control number 0551–0014 in the subject line of the message.
- *Fax:* 202–720–0876.
- *Mail:* U.S. Department of Agriculture, 1400 Independence Avenue SW, Washington, DC 20250–1021.

FOR FURTHER INFORMATION CONTACT: *William.Janis@usda.gov,* 202–720–2194, *William.Janis@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Certificates for Quota Eligibility.

OMB Number: 0551–0014.

Expiration Date of Approval: April 30, 2020.

Type of Request: Revision of a currently approved information collection.

Abstract: Additional U.S. note 5 to Chapter 17 of the Harmonized Tariff Schedule of the United States (HTS), established by Presidential Proclamation 6763 of December 1994, authorizes the Secretary of Agriculture to establish for each fiscal year the quantity of sugars, syrups, and molasses that may be entered at the lower tariff rates of TRQs established under the Uruguay Round of multilateral trade negotiations as reflected in the provisions of Schedule XX (United States), annexed to the Marrakesh Agreement Establishing the World Trade Organization (WTO).

Pursuant to 15 CFR part 2011, Allocation of Tariff-Rate Quota on Imported Sugars, Syrups, and Molasses, Subpart A—Certificates of Quota, CQEs are issued to foreign countries that have been allocated a share of the WTO sugar TRQ. This regulation provides for the issuance of CQEs by the Secretary of Agriculture and in general prohibits sugar entered under the WTO TRQ from being imported into the United States or withdrawn from a warehouse for consumption at the in-quota duty rates unless such sugar is accompanied by a valid CQE.

In addition, CQEs are required for the import of sugar into the United States under the sugar TRQs established under the U.S.—Colombia, U.S.—Panama, and U.S.—Peru Trade Promotion Agreements, as set forth in 19 U.S.C. 3805.

CQEs for the aforementioned WTO and FTA sugar TRQs are distributed to foreign countries by the Senior Director of the Multilateral Affairs Division, Foreign Agriculture Service, or his or her designee. The distribution of CQEs is in such amounts and at such times as the Senior Director determines are appropriate to enable the foreign country to fill its quota allocation for such quota period in a reasonable manner, taking into account harvesting periods, U.S. import requirements, and other relevant factors. The information required to be collected on the CQE is used to monitor and control the imports of products subject to the WTO and FTA sugar TRQs. A valid CQE, duly executed and issued by the Certifying Authority of the foreign country, is required for eligibility to enter the products into U.S. customs territory under the TRQs.

Estimate of burden: The public reporting burden for the collection directly varies with the number of CQEs issued.

Respondents: Foreign governments.

Estimated Number of WTO Respondents: 30.

Estimated Number of FTA Respondents: 2.

Estimated Number of Responses per Respondent: 124 per fiscal year.

Estimated Total Annual Reporting Burden: 3,968 hours

Copies of this information collection can be obtained from Connie Ehrhart, the Agency Information Collection Coordinator, at (202) 690–1578.

Requests for Comments: Send comments regarding (a) Whether the information collection 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 of the collection of information including validity of the methodology and assumption 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 through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Copies of this information collection may be obtained from Ronald Croushorn, the Agency Information Collection Coordinator, at (202) 720–3038.

Comments may be sent to William Janis, International Economist, Multilateral Affairs Division, AgStop 1021, U.S. Department of Agriculture, 1400 Independence Avenue SW, Washington, DC 20250–1021 or telephone (202) 720–2194 or email *William.Janis@usda.gov.* All comments received will be available for public inspection in Room 5526 at the above address.

Persons with disabilities who require an alternative means of communication for information (Braille, large print, audiotape, etc.) should contact USDA's target center at (202) 720–2600 (voice and TDD). All responses to this notice will be summarized and included in the request for OMB approval. All comments also will become a matter of public record.

FAS is committed to complying with the Government Paperwork Elimination Act which requires Government agencies, to the maximum extent feasible, to provide the public the option of electronically submitting information collection. CQEs permit exporters to ship raw cane sugar to the United States at the U.S. sugar price, which is ordinarily higher than the world sugar price. Therefore, in contrast to most information collection documents, CQEs have a monetary value equivalent to the substantial benefits to exporters. CQEs have always been carefully handled as secure documents and distributed only to foreign government-approved Certifying Authorities.

Dated: February 7, 2020.

Kenneth Isley,

Administrator, Foreign Agricultural Service.

[FR Doc. 2020–03133 Filed 2–14–20; 8:45 am]

BILLING CODE 3410–10–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 Monday, February 24, 2020 at 4 p.m. (EST). The purpose of the meeting is to discuss next steps following the publication of the Committee's civil rights project report on the agency's website, and recruitment of potential candidates for appointment to the DE Advisory Committee—members terms end June 16, 2020.

DATES: Monday, February 24, 2020 at 4 p.m. (EST).

Public Call-In Information: Conference call number: 1–866–556–2429 and conference call ID: 4512490.

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: 1–866–556–2429 and conference call ID: 4512490. 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: 1–866–556–2429 and conference call ID: 4512490.

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: *https://gsageo.force.com/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzlEAAQ,* 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

Monday, February 24, 2020 at 4:00 p.m. (EST)

I. Welcome and Roll Call
II. Discussion
—Next steps following publication of the Committee's civil rights project report
—Recruitment of potential candidates for appointment to the DE Advisory Committee
III. Other Business
IV. Public Comments
V. Next Meeting
VI. Adjourn

Dated: February 12, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–03150 Filed 2–14–20; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Indiana 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 Indiana Advisory Committee (Committee) will hold a public briefing on Thursday, February 27, 2020, for the purpose of discussing the civil rights implications of indoor and outdoor lead exposure in the state.

DATES: The meeting will be held on Thursday, February 27, 2020, from 9:00 a.m.–2:00 p.m. Eastern Time.

ADDRESSES: Ivy Technical Community College, The Event Center, 2820 N Meridian Street, Indianapolis, IN 46208.

FOR FURTHER INFORMATION CONTACT: David Barreras, DFO, at *dbarreras@usccr.gov* or 312–353–8311.

SUPPLEMENTARY INFORMATION: This meeting is free and open to the public. Members of the public may attend and speak to the committee at the designated time for open forum. Members of the public will be invited to make a statement as time allows. Speakers will be asked to identify themselves, the organization they are affiliated with (if any), and an email address prior to addressing the committee.

Members of the public are also entitled to submit written comments; the comments must be received within 30 days following the briefing. Written comments may be mailed to the Advisory Committee Management Unit, U.S. Commission on Civil Rights, 230 S Dearborn, Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353–8324 or emailed to David Barreras at *dbarreras@usccr.gov.* Persons who desire additional information may contact the Committee Management Office at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Committee Management Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Indiana Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit Office at the above email or street address.

Agenda

9:00 a.m.—Welcome, Introductions, and Chair's comments
9:15 a.m.—Panel I
10:15 a.m.—Panel II
11:15 a.m.—Panel III
12:30 p.m.—Break
1:00 p.m.—Panel IV
1:45 p.m.—Open Forum
2:00 p.m.—Adjournment

Dated: February 12, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–03112 Filed 2–14–20; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Wyoming Advisory Committee

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 (FACA) that the meeting of the Wyoming Advisory Committee (Committee) to the Commission will be held at 1:00 p.m. (MDT) Friday, March 20, 2020. The purpose of this meeting is to discuss potential findings and recommendations that will be included in their hate crimes report.

DATES: Friday, March 20, 2020 at 1:00 p.m. MDT.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes (DFO) at *afortes@usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION:

Public Call Information: Dial: 800–367–2403; Conference ID: 7266173.

This meeting is available to the public through the following toll-free call-in number: 800–367–2403, conference ID number: 7266173. Any interested member of the public may call this number and listen to the meeting. 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. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012. They may be faxed to the Commission at (213) 894–0508, or emailed Ana Victoria Fortes at *afortes@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (213) 894–3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meetings at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzliAAA.*

Please click on ''Committee Meetings'' tab. Records generated from these meetings may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meetings. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome
II. Follow-up on Outstanding Items
  a. Status of civilian oversight boards throughout Wyoming counties
III. Discuss Findings and Recommendations
IV. Public Comment
V. Adjournment

Dated: February 12, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–03193 Filed 2–14–20; 8:45 am]

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COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the District of Columbia Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a meeting of the District of Columbia Advisory Committee to the Commission will convene by conference call, at 11:30 a.m. (EST) Thursday, March 5, 2020. The purpose of the planning meeting is to discuss the status of minor clarifying edits from Committee members and expert presenters who participated in the DC Mental Health Court briefings; panel summaries prepared by several Committee members; the proposed report draft.

DATES: Thursday, March 5, 2020 at 11:30 a.m. (EST).

Public Call-In Information: Conference call number: 1–877–260–1479 and conference call ID number: 1929821.

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: 1–877–260–1479 and conference call ID number: 1929821. 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: 1–877–260–1479 and conference call ID number: 1929821.

Members of the public are invited to make statements during the Public Comments section of the meeting or to submit written comments. The comments must be received in the regional office by Friday, March 6, 2020. 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: *https://gsageo.force.com/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzlKAAQPlease* 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 meeting. 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 numbers, email or street address.

Agenda

Thursday, March 5, 2020, at 11:30 a.m. (EST)

I. Welcome and Rollcall
II. Planning Meeting
—discuss the status of minor clarifying edits from Committee members and expert presenters who participated in the DC Mental Health Court briefings
—discuss panel summaries prepared by several Committee members
—discuss proposed report draft
III. Other Business
IV. Next Planning Meeting
V. Public Comments
VI. Adjourn

Dated: February 12, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–03151 Filed 2–14–20; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–119]

Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof From the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable February 4, 2020.

FOR FURTHER INFORMATION CONTACT: Leo Ayala, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3945.

SUPPLEMENTARY INFORMATION:

The Petition

On January 15, 2020, the U.S. Department of Commerce (Commerce) received an antidumping duty (AD) petition concerning imports of certain vertical shaft engines between 225cc and 999cc, and parts thereof (vertical shaft engines) from the People's Republic of China (China), filed in proper form on behalf of the Coalition of American Vertical Engine Producers (the petitioner or the Coalition).[1] The Petition was accompanied by a countervailing duty (CVD) petition concerning imports of vertical shaft engines from China.

On January 17, 2020, Commerce requested supplemental information pertaining to certain aspects of the Petition,[2] to which the petitioner filed its response on January 22, 2020.[3] On January 27, 2020, Commerce had a phone conversation with the petitioner requesting that it address certain issues.[4] The petitioner filed responses to these requests on January 29, 2020.[5]

In accordance with section 732(b) of the Tariff Act of 1930, as amended (the Act), the petitioner alleges that imports of vertical shaft engines from China are being, or are likely to be, sold in the United States at less than fair value (LTFV) within the meaning of section 731 of the Act, and that such imports are materially injuring, or threatening material injury to, the domestic industry producing vertical shaft engines in the United States. Consistent with section 732(b)(1) of the Act, the Petition is accompanied by information reasonably available to the petitioner supporting its allegations.

Commerce finds that the petitioner filed the Petition on behalf of the domestic industry, because the petitioner is an interested party, as defined in sections 771(9)(C) and (F) of the Act. Commerce also finds that the

[1] *See* Petitioner's Letter, ''Petitions for the Imposition of Antidumping and Countervailing Duties on Certain Vertical Shaft Engines between 225cc and 999cc, and Parts Thereof from the People's Republic of China,'' dated January 15, 2020 (the Petition).

[2] *See* Commerce's Letter, ''Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of certain vertical shaft engines between 225cc and 999cc, and parts thereof from the People's Republic of China: Supplemental Questions Concerning Volume II,'' dated January 17, 2020.

[3] *See* Petitioner's Letter, ''Responses to Supplemental Questions Concerning Volume II of the Petitions for the Imposition of Antidumping and Countervailing Duties Pursuant to Sections 701 and 731 of the Tariff Act of 1930, As Amended on Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the People's Republic of China,'' dated January 22, 2020 (AD Supplement); *see also* Petitioner's Letter, ''Responses to Supplemental Questions Concerning Volume I of the Petitions for the Imposition of Antidumping and Countervailing Duties Pursuant to Sections 701 and 731 of the Tariff Act of 1930, As Amended on Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the People's Republic of China,'' dated January 22, 2020 (General Issues Supplement).

[4] *See* Memorandum, ''Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from The People's Republic of China: Call to Counsel,'' dated January 27, 2020.

[5] *See* Petitioner's Letter, ''Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the People's Republic of China: Responses to Second Supplemental Questions Concerning Volume II of the Petitions,'' dated January 29, 2020 (AD Second Supplement); *see also* Petitioner's Letter, ''Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the People's Republic of China: Responses to Second Supplemental Questions Concerning Volume I of the Petitions,'' dated January 29, 2020 (Second General Issues Supplement).

petitioner demonstrated sufficient industry support with respect to the initiation of the requested AD investigation.[6]

Period of Investigation

Because China is a non-market economy (NME) country, pursuant to 19 CFR 351.204(b)(1), and because the Petition was filed on January 15, 2020, the period of investigation (POI) is July 1, 2019 through December 31, 2020.

Scope of the Investigation

The merchandise covered by this investigation is vertical shaft engines from China. For a full description of the scope of this investigation, *see* the appendix to this notice.

Comments on Scope of the Investigation

As discussed in the *Preamble* to Commerce's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage (*i.e.,* scope).[7] Commerce will consider all comments received from interested parties and, if necessary, will consult with interested parties prior to the issuance of the preliminary determination. If scope comments include factual information,[8] all such factual information should be limited to public information. To facilitate preparation of its questionnaires, Commerce requests that all interested parties submit scope comments by 5:00 p.m. Eastern Time (ET) on February 24, 2020, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. ET on March 5, 2020, which is 10 calendar days from the initial comment deadline.[9]

Commerce requests that any factual information the parties consider relevant to the scope of the investigation be submitted during this time period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigation may be relevant, the party may contact Commerce and request permission to submit the additional information. All such comments must also be filed on the record of the concurrent AD and CVD investigations.

Filing Requirements

All submissions to Commerce must be filed electronically using Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS).[10] An electronically filed document must be received successfully in its entirety by the time and date it is due. Documents exempted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

Comments on Product Characteristics for AD Questionnaires

Commerce is providing interested parties an opportunity to comment on the appropriate physical characteristics of vertical shaft engines to be reported in response to Commerce's AD questionnaire. This information will be used to identify the key physical characteristics of the subject merchandise in order to report the relevant factors of production (FOPs) accurately, as well as to develop appropriate product-comparison criteria.

Interested parties may provide any information or comments that they believe are relevant to the development of an accurate list of physical characteristics. In order to consider the suggestions of interested parties in developing and issuing the AD questionnaire, all comments must be filed by 5:00 p.m. ET on February 24, 2020, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. ET on March 5, 2020, which is 10 calendar days from the initial comment deadline.[11] All comments and submissions to Commerce must be filed electronically using ACCESS, as explained above, on the record of this AD investigation.

Determination of Industry Support for the Petition

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, Commerce shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs Commerce to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both Commerce and the ITC must apply the same statutory definition regarding the domestic like product,[12] they do so for different purposes and pursuant to a separate and distinct authority. In addition, Commerce's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[13]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioner does not offer a

[6] *See* ''Determination of Industry Support for the Petition'' section, *infra.*

[7] *See Antidumping Duties; Countervailing Duties,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

[8] *See* 19 CFR 351.102(b)(21) (defining ''factual information'').

[9] *See* 19 CFR 351.303(b).

[10] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011); *see also Enforcement and Compliance; Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014) for details of Commerce's electronic filing requirements, effective August 5, 2011. Information on using ACCESS can be found at *https://access.trade.gov/help.aspx* and a handbook can be found at *https://access.trade.gov/help/Handbook%20on%20Electronic%20Filling%20Procedures.pdf.*

[11] *See* 19 CFR 351.303(b).

[12] *See* section 771(10) of the Act.

[13] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

definition of the domestic like product distinct from the scope of the investigation.[14] Based on our analysis of the information submitted on the record, we have determined that vertical shaft engines, as defined in the scope, constitute a single domestic like product, and we have analyzed industry support in terms of that domestic like product.[15]

In determining whether the petitioner has standing under section 732(c)(4)(A) of the Act, we considered the industry support data contained in the Petition with reference to the domestic like product as defined in the ''Scope of the Investigation,'' in the appendix to this notice. To establish industry support, the petitioner provided 2019 shipments of the domestic like product for members of the Coalition.[16] The petitioner estimated the production of the domestic like product for the entire domestic industry based on U.S. shipment data, export data, and its own knowledge of the industry, because shipments and production of vertical shaft engines correlate with one another and shipments are a reasonable proxy for production in the vertical shaft engines industry.[17] The petitioner compared the 2019 shipments of the Coalition to the estimated total shipments of the domestic like product for the entire domestic industry.[18] We relied on data provided by the petitioner for purposes of measuring industry support.[19]

Our review of the data provided in the Petition, the General Issues Supplement, the Second General Issues Supplement, and other information readily available to Commerce indicates that the petitioner has established industry support for the Petition.[20] First, the Petition established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, Commerce is not required to take further action in order to evaluate industry support (*e.g.,* polling).[21] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petition account for at least 25 percent of the total production of the domestic like product.[22] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition.[23] Accordingly, Commerce determines that the Petition was filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.[24]

Allegations and Evidence of Material Injury and Causation

The petitioner alleges that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the imports of the subject merchandise sold at LTFV. In addition, the petitioner alleges that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[25]

The petitioner contends that the industry's injured condition is illustrated by a significant and increasing volume of subject imports; reduced market share; underselling and price depression or suppression; lost sales and revenues; and a decline in the domestic industry's financial performance and profitability.[26] We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, causation, as well as negligibility, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.[27]

Allegations of Sales at Less Than Fair Value

The following is a description of the allegation of sales at LTFV upon which Commerce based its decision to initiate an AD investigation of vertical shaft engines from China. The sources of data for the deductions and adjustments relating to U.S. price and normal value (NV) are discussed in greater detail in the AD Initiation Checklist.

Export Price

The petitioner based export price (EP) on sales offers to customers in the United States for the sale of vertical shaft engines produced in and exported from China.[28] In order to calculate ex-factory U.S. prices, where appropriate, the petitioner made deductions from U.S. prices for foreign inland freight and foreign brokerage and handling.[29]

Normal Value

Commerce considers China to be a non-market economy (NME) country.[30] In accordance with section 771(18)(C)(i) of the Act, any determination that a foreign country is an NME country shall remain in effect until revoked by Commerce. Therefore, we continue to treat China as an NME country for purposes of the initiation of this investigation. Accordingly, NV in China is appropriately based on FOPs valued in a surrogate market economy country,

[14] *See* Volume I of the Petition, at 16–17; *see also* General Issues Supplement at 3–5.

[15] For a discussion of the domestic like product analysis as applied to this case and information regarding industry support, *see* Antidumping Duty Investigation Initiation Checklist: Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the People's Republic of China (China AD Initiation Checklist) at Attachment II, ''Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the People's Republic of China'' (Attachment II), dated concurrently with this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Commerce building.

[16] *See* Volume I of the Petition, at 2–3 and Exhibits I–5 and I–6; *see also* General Issues Supplement at 6–9 and Exhibits Supp–I–2 and Supp–I–3; and Second General Issues Supplement, at Exhibit Supp–I–2.

[17] *See* Volume I of the Petition, at Exhibit I–6; *see also* General Issues Supplement, at 6–9 and Exhibits Supp–I–2 and Supp–I–3; and Second General Issues Supplement, at Exhibit 2Supp–I–2.

[18] *See* General Issues Supplement, at 6–9 and Exhibits Supp–I–2 and Supp–I–3.

[19] *See* Volume I of the Petition, at 2–3 and Exhibits I–5 and I–6; *see also* General Issues Supplement at 6–9 and Exhibits Supp–I–2 and Supp–I–3; and Second General Issues Supplement, at Exhibit Supp–I–2. For further discussion, *see* China AD Initiation Checklist, at Attachment II.

[20] *See* China AD Initiation Checklist, at Attachment II.

[21] *See* section 732(c)(4)(D) of the Act; *see also* China AD Initiation Checklist, at Attachment II.

[22] *See* China AD Initiation Checklist, at Attachment II.

[23] *Id.*

[24] *Id.*

[25] *See* Volume I of the Petition, at 23–24.

[26] *See* Volume I of the Petition, at 13–15, 22–35 and Exhibits I–5 and I–11 through I–24.

[27] *See* China AD Initiation Checklist, at Attachment III, ''Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Vertical Shaft Engines Between 225cc and 999cc, and Parts thereof from the People's Republic of China'' (Attachment III).

[28] *See* Volume II of the Petition, at 1–2 and Exhibits II–1.

[29] *See* Volume II of the Petition, at 4–8 and Exhibits II–2, II–4, II–5A, II–5B, II–6, and II–7; *see also* AD Supplement, at 1 and Exhibits II–Supp–3.

[30] *See Antidumping Duty Investigation of Certain Aluminum Foil from the People's Republic of China: Affirmative Preliminary Determination of Sales at Less-Than-Fair Value and Postponement of Final Determination,* 82 FR 50858, 50861 (November 2, 2017), and accompanying Preliminary Decision Memorandum at ''*China's Status as a Non-Market Economy,*'' unchanged in *Certain Aluminum Foil from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 83 FR 9282 (March 5, 2018).

in accordance with section 773(c) of the Act.[31]

The petitioner claims that Turkey is an appropriate surrogate country for China, because it is a market economy country that is at a level of economic development comparable to that of China and it is a significant producer of comparable merchandise.[32] The petitioner valued direct material inputs and packing materials using Trade Data Monitor, data from the International Energy Agency to value electricity and natural gas, and data from the International Labor Organization to value labor.[33] Based on the information provided by the petitioner, we determine that it is appropriate to use Turkey as a surrogate country for purposes of initiation.[34]

Interested parties will have the opportunity to submit comments regarding surrogate country selection and, pursuant to 19 CFR 351.301(c)(3)(i), will be provided an opportunity to submit publicly available information to value FOPs, within 30 days before the scheduled date of the preliminary determination.

Factors of Production

Because information regarding the volume of inputs consumed by Chinese producers/exporters were not reasonably available, the petitioner used the product-specific consumption rates of a U.S. vertical shaft engines producer as a surrogate to estimate a Chinese manufacturer's FOPs.[35] The petitioner valued the estimated FOPs using surrogate values from Turkey.[36] The petitioner calculated factory overhead, selling, general and administrative expenses, and profit based on the experience of a Turkish producer of comparable merchandise (*i.e.,* radiators, boilers, heat pumps, motors, and other products).[37]

Fair Value Comparisons

Based on the data provided in the Petition, there is reason to believe that imports of vertical shaft engines from China are being, or are likely to be, sold in the United States at LTFV. Based on comparisons of EP to NV, in accordance with sections 772 and 773 of the Act, the estimated dumping margins for vertical shaft engines from China range from 324.73 percent to 637.73 percent.[38]

Initiation of LTFV Investigation

We find that the Petition on vertical shaft engines from China, we find that the Petition meets the requirements of section 732 of the Act. Therefore, we are initiating an AD investigation to determine whether imports of vertical shaft engines from China are being, or are likely to be, sold in the United States at LTFV. In accordance with section 733(b)(1)(A) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determination no later than 140 days after the date of this initiation.

Critical Circumstances

The petitioner alleges, based on trade statistics and documented prior knowledge of an impending trade case, that there is a reasonable basis to believe or suspect that critical circumstances exist with regard to imports of vertical shaft engines from China.[39]

Section 733(e)(1) of the Act states that if a petitioner alleges critical circumstances, Commerce will find that such circumstances exist, at any time after the date of initiation, when there is a reasonable basis to believe or suspect that under, subparagraph (A)(i), there is a history of dumping and there is material injury by reason of dumped imports in the United States or elsewhere of the subject merchandise, or (ii) the person by whom, or for whose account, the merchandise was imported knew or should have known that the exporter was selling the subject merchandise at less than its fair value and that there was likely to be material injury by reason of such sales, and (B) that ''there have been massive imports of the subject merchandise over a relatively short period.'' Section 351.206(h)(2) of Commerce's regulations provides that, generally, imports must increase by at least 15 percent during the ''relatively short period'' to be considered ''massive'' and section 351.206(i) defines a ''relatively short period'' as normally being the period beginning on the date the proceeding begins (*i.e.,* the date the petition is filed)[40] and ending at least three months later.[41] The regulations also provide, however, that if Commerce ''finds that importers, or exporters and producers, had reason to believe, at some time prior to the beginning of the proceeding, that a proceeding was likely,'' Commerce ''may consider a period of not less than three months from that earlier time.''[42]

The petitioner alleges that there is a history of dumping and material injury by reason of dumped imports of vertical shaft engines, and that U.S. importers knew or should have known that vertical shaft engines were being sold at LTFV and that there was likely to be material injury by reason of such sales.[43] The petitioner notes that the dumping margins calculated in Volume II of the Petition range from approximately 320% to over 630%, which exceed the 25 percent threshold used by Commerce to impute knowledge of dumping.[44]

The petitioner also asserts that there have been massive imports of vertical shaft engines over a relatively short period. Based on the petitioner's calculation, the imports of engines in the classification that most closely approximates vertical shaft engines surged 35.7 percent between June 2019 through November 2019 against the same period in calendar year 2018.[45] The petitioner chose these base and comparison periods in order to account for seasonality and the unusual circumstances caused by the imposition of 25 percent Section 301 duties, in accordance with 19 CFR 351.206(h)(1)(ii). The petitioner asserts that, because the surge in imports constituted more than a 15 percent change, import volumes of vertical shaft engines are massive, as defined in Commerce's regulations.

The petitioner requests that Commerce make a preliminary finding of critical circumstances within 45 days of the filing of the Petition.[46] Section 732(e) of the Act states that when there is a reasonable basis to believe or suspect (1) there is a history of dumping in the United States or elsewhere of the subject merchandise, or (2) the person by whom, or for whose account, the merchandise was imported knew, or should have known, that the exporter was selling the subject merchandise at LTFV, Commerce may request that U.S. Customs and Border Protection (CBP) compile information on an expedited basis regarding entries of the subject merchandise.

Taking into consideration the foregoing, we will analyze this matter further. We will monitor imports of

[31] *See* China AD Initiation Checklist.

[32] *See* Volume II of the Petition, at 2 and 9 and Exhibits II–8.

[33] *Id.* at Exhibit II–15, Exhibit II–16, Exhibit II–17, Exhibit II–18, and Exhibit II–20.

[34] *See* China AD Initiation Checklist.

[35] *Id.* at 10 and 13 and Exhibits II–10.

[36] *Id.* at 10 and Exhibits II–10.

[37] *See* Volume II of the Petition, at 16–18 and Exhibits II–21A, II–21B, and II–11; *see also* AD Supplement, at 5–8 and Exhibits II–Supp–11 and II–Supp–21A.

[38] *See* AD supplement at 2 and Exhibit II–Supp–4; *see also* China AD Initiation Checklist.

[39] *See* Volume IV of the Petition, at 1–11.

[40] *See* 19 CFR 351.102(b)(40) (providing that a proceeding begins on the date of the filing of a petition).

[41] *See* 19 CFR 351.206(i).

[42] *Id.*

[43] *See* Volume IV of the Petition, at 7.

[44] *Id.* at 7–8.

[45] *Id.* at 5–6.

[46] *Id.* at 11.

vertical shaft engines from China and may request that CBP compile information on an expedited basis regarding entries of subject merchandise.[47] If, at any time, the criteria for a finding of critical circumstances are established, we will issue a critical circumstances determination at the earliest possible date.[48]

Respondent Selection

The petitioner named 35 companies in China as producers/exporters of vertical shaft engines.[49] In accordance with our standard practice for respondent selection in AD investigations involving NME countries, Commerce selects respondents based on quantity and value (Q&V) questionnaires in cases where it has determined that the number of companies is large and it cannot individually examine each company based upon its resources. After considering the large number of producers and exporters identified in the Petition, and considering the resources that must be used by Commerce to send Q&V questionnaires to all of these companies, Commerce has determined that it does not have sufficient administrative resources to send Q&V questionnaires to all 35 identified producers and exporters. Therefore, Commerce has determined to limit the number of Q&V questionnaires that it will send out to exporters and producers based on CBP data for U.S. imports of vertical shaft engines during the POI under the appropriate Harmonized Tariff Schedule of the United States numbers listed in the ''Scope of the Investigation,'' in the appendix. Accordingly, Commerce will send Q&V questionnaires to the largest producers and exporters that are identified in the CBP data for which there is address information on the record.

On February 4, 2020, Commerce released CBP data on imports of vertical shaft engines from China under administrative protective order (APO) to all parties with access to information protected by APO, and indicated that interested parties wishing to comment on the CBP data must do so within three business days of the publication date of the notice of initiation of this investigation.[50] We further stated that we will not accept rebuttal comments.

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on the Commerce website at *http://enforcement.trade.gov/apo.*

Comments must be filed electronically using ACCESS. An electronically filed document must be received successfully, in its entirety, by ACCESS no later than 5:00 p.m. ET on the deadline noted above. Commerce intends to finalize its decisions regarding respondent selection within 20 days of publication of this notice.

In addition, Commerce will post the Q&V questionnaire along with filing instructions on Enforcement and Compliance's website at *http://www.trade.gov/enforcement/news.asp.* In accordance with the standard practice for respondent selection in AD cases involving NME countries, Commerce intends to base respondent selection on the responses to the Q&V questionnaire that it receives.

Producers/exporters of vertical shaft engines from China that do not receive Q&V questionnaires may still submit a response to the Q&V questionnaire and can obtain a copy of the Q&V questionnaire from Enforcement & Compliance's website. The Q&V questionnaire response must be submitted by the relevant China exporters/producers no later than February 14, 2020. All Q&V questionnaire responses must be filed electronically via ACCESS.

Separate Rates

In order to obtain separate-rate status in an NME investigation, exporters and producers must submit a separate-rate application.[51] The specific requirements for submitting a separate-rate application in a China investigation are outlined in detail in the application itself, which is available on Commerce's website at *http://enforcement.trade.gov/nme/nme-sep-rate.html.* The separate-rate application will be due 30 days after publication of this initiation notice.[52] Exporters and producers who submit a separate-rate application and have been selected as mandatory respondents will be eligible for consideration for separate-rate status only if they respond to all parts of Commerce's AD questionnaire as mandatory respondents. Commerce requires that companies from China submit a response to both the Q&V questionnaire and the separate-rate application by the respective deadlines in order to receive consideration for separate-rate status. Companies not filing a timely Q&V questionnaire response will not receive separate rate consideration.

Use of Combination Rates

Commerce will calculate combination rates for certain respondents that are eligible for a separate rate in an NME investigation. The Separate Rates and Combination Rates Bulletin states:

> {w}hile continuing the practice of assigning separate rates only to exporters, all separate rates that Commerce will now assign in its NME Investigation will be specific to those producers that supplied the exporter during the period of investigation. Note, however, that one rate is calculated for the exporter and all of the producers which supplied subject merchandise to it during the period of investigation. This practice applies both to mandatory respondents receiving an individually calculated separate rate as well as the pool of non-investigated firms receiving the weighted-average of the individually calculated rates. This practice is referred to as the application of ''combination rates'' because such rates apply to specific combinations of exporters and one or more producers. The cash-deposit rate assigned to an exporter will apply only to merchandise both exported by the firm in question *and* produced by a firm that supplied the exporter during the period of investigation.[53]

Distribution of Copies of the Petition

In accordance with section 732(b)(3)(A) of the Act and 19 CFR 351.202(f), a copy of the public version of the Petition has been provided to the Government of China via ACCESS.

Furthermore, to the extent practicable, Commerce will attempt to provide a copy of the public version of the Petition to each exporter named in the Petition, as provided under 19 CFR 351.203(c)(2).

ITC Notification

Commerce will notify the ITC of its initiation, as required by section 732(d) of the Act.

Preliminary Determinations by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petition was filed, whether there is a reasonable indication that imports of

[47] *See* section 732(e) of the Act.

[48] *See Change in Policy Regarding Timing of Issuance of Critical Circumstances Determinations,* 63 FR 55364 (October 15, 1998).

[49] *See* Volume I of the Petition, at Exhibit I–10.

[50] *See* Memorandum, ''Antidumping Duty Investigation of Certain Vertical Shaft Engines between 225cc and 999cc, and Parts Thereof From the People's Republic of China: Release of U.S. Customs and Border Protection Data,'' dated February 4, 2020.

[51] *See* Policy Bulletin 05.1: Separate-Rates Practice and Application of Combination Rates in Antidumping Investigation involving Non-Market Economy Countries (April 5, 2005), available at *http://enforcement.trade.gov/policy/bull05-1.pdf* (Policy Bulletin 05.1).

[52] Although in past investigations this deadline was 60 days, consistent with 19 CFR 351.301(a), which states that ''the Secretary may request any person to submit factual information at any time during a proceeding,'' this deadline is now 30 days.

[53] *See* Policy Bulletin 05.1, at 6 (emphasis added).

vertical shaft engines from China are materially injuring or threatening material injury to a U.S. industry.[54] A negative ITC determination will result in the investigation being terminated.[55] Otherwise, this investigation will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). Any party, when submitting factual information, must specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted [56] and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.[57] Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Please review the regulations prior to submitting factual information in this investigation.

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by Commerce. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. ET on the due date. Under certain circumstances, Commerce may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, Commerce will inform parties in a letter or memorandum of the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, standalone submission; under limited circumstances Commerce will grant untimely filed requests for the extension of time limits. Parties should review *Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting extension requests or factual information in this investigation.

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[58] Parties must use the certification formats provided in 19 CFR 351.303(g).[59] Commerce intends to reject factual submissions if the submitting party does not comply with the applicable certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. Instructions for filing such applications may be found on the Commerce website at *http://enforcement.trade.gov/apo.*

On January 22, 2008, Commerce published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Parties wishing to participate in this investigation should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed in 19 CFR 351.103(d)).

This notice is issued and published pursuant to sections 732(c)(2) and 777(i) of the Act, and 19 CFR 351.203(c).

Dated: February 4, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Investigation

The merchandise covered by this investigation consists of spark-ignited, non-road, vertical shaft engines, whether finished or unfinished, whether assembled or unassembled, primarily for riding lawn mowers and zero-tum radius lawn mowers. Engines meeting this physical description may also be for other non-hand-held outdoor power equipment such as, including but not limited to, tow-behind brush mowers, grinders, and vertical shaft generators. The subject engines are spark ignition, single or multiple cylinder, air cooled, internal combustion engines with vertical power take off shafts with a minimum displacement of 225 cubic centimeters (cc) and a maximum displacement of 999cc. Typically, engines with displacements of this size generate gross power of between 6.7 kilowatts (kw) to 42 kw.

Engines covered by this scope normally must comply with and be certified under Environmental Protection Agency (EPA) air pollution controls title 40, chapter I, subchapter U, part 1054 of the Code of Federal Regulations standards for small non-road spark-ignition engines and equipment. Engines that otherwise meet the physical description of the scope but are not certified under 40 CFR part 1054 and are not certified under other parts of subchapter U of the EPA air pollution controls are not excluded from the scope of this proceeding. Engines that may be certified under both 40 CFR part 1054 as well as other parts of subchapter U remain subject to the scope of this proceeding.

For purposes of this investigation, an unfinished engine covers at a minimum a sub-assembly comprised of, but not limited to, the following components: crankcase, crankshaft, camshaft, piston(s), and connecting rod(s). Importation of these components together, whether assembled or unassembled, and whether or not accompanied by additional components such as an oil pan, manifold, cylinder head(s), valve train, or valve cover(s), constitutes an unfinished engine for purposes of this investigation. The inclusion of other products such as spark plugs fitted into the cylinder head or electrical devices (*e.g.,* ignition modules, ignition coils) for synchronizing with the motor to supply tension current does not remove the product from the scope. The inclusion of any other components not identified as comprising the unfinished engine subassembly in a third country does not remove the engine from the scope.

The engines subject to this investigation are typically classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings: 8407.90.1020, 8407.90.1060, and 8407.90.1080. The engine subassemblies that are subject to this investigation enter under HTSUS 8409.91.9990. Engines subject to this investigation may also enter under HTSUS 8407.90.9060 and 8407.90.9080. The HTSUS subheadings are provided for convenience and customs purposes only, and the written description of the merchandise under investigation is dispositive.

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[54] *See* section 733(a) of the Act.

[55] *Id.*

[56] *See* 19 CFR 351.301(b).

[57] *See* 19 CFR 351.301(b)(2).

[58] *See* section 782(b) of the Act.

[59] *See Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*). Answers to frequently asked questions regarding the *Final Rule* are available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–856]

Certain Corrosion-Resistant Steel Products From Taiwan: Affirmative Preliminary Determination of Circumvention Inquiry Involving Malaysia

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that imports of certain corrosion-resistant steel products (CORE) completed in Malaysia, using hot-rolled steel (HRS) and/or cold-rolled steel (CRS) flat products manufactured in Taiwan, are circumventing the antidumping duty (AD) order on CORE from Taiwan.

DATES: Applicable February 18, 2020.

FOR FURTHER INFORMATION CONTACT: Shanah Lee and Stephanie Berger, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6386 and (202) 482–2483, respectively.

SUPPLEMENTARY INFORMATION:

Background

On August 12, 2019, Commerce self-initiated a country-wide anti-circumvention inquiry of the *Taiwan CORE Order*[1] covering Taiwanese-origin HRS and/or CRS exported to Malaysia for completion into CORE and subsequently exported to the United States.[2] In the *Initiation Notice,* Commerce initiated the instant anti-circumvention inquiry based on available information and an analysis pursuant to section 781(b) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.225(h), to determine whether the importation of Taiwanese-origin HRS or CRS substrate for completion into CORE in Malaysia and subsequent sale of that CORE to the United States constitutes circumvention of the *Taiwan CORE Order.*

For a complete description of the record developed since the initiation of this inquiry, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Order

The products covered by this order are certain flat-rolled steel products, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel- or iron-based alloys, whether or not corrugated or painted, varnished, laminated, or coated with plastics or other non-metallic substances in addition to the metallic coating. For a complete description of the scope of the order, *see* the Preliminary Decision Memorandum.

Scope of the Anti-Circumvention Inquiry

This anti-circumvention inquiry covers CORE completed in Malaysia from HRS and/or CRS substrate input manufactured in Taiwan and subsequently exported from Malaysia to the United States (merchandise subject to this inquiry).

Methodology

Commerce is conducting this anti-circumvention inquiry in accordance with section 781(b) of the Act. Because certain interested parties did not cooperate to the best of their abilities in responding to Commerce's requests for information, we have based parts of our preliminary determination on the facts available, with adverse inferences, pursuant to sections 776(a) and (b) of the Act. For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

Preliminary Finding

As detailed in the Preliminary Decision Memorandum, we preliminarily determine that CORE completed in Malaysia from HRS and/or CRS substrate sourced from Taiwan is circumventing the *Taiwan CORE Order.* We therefore preliminarily determine that it is appropriate to include this merchandise within the *Taiwan CORE Order* and to instruct U.S. Customs and Border Protection (CBP) to suspend any entries of CORE from Malaysia produced from HRS and/or CRS from Taiwan.

Suspension of Liquidation

As stated above, Commerce has made a preliminary affirmative determination that imports of CORE completed in Taiwan, using HRS and/or CRS flat products manufactured in China, are circumventing the *Taiwan CORE Order.* In accordance with 19 CFR 351.225(l)(2), Commerce will direct CBP to suspend liquidation and to require a cash deposit of estimated duties on unliquidated entries of CORE produced in Malaysia, as appropriate, that were entered, or withdrawn from warehouse, for consumption on or after August 12, 2019, the date of initiation of the anti-circumvention inquiry. The suspension of liquidation instructions will remain in effect until further notice.

CORE produced in Malaysia from HRS and/or CRS that is not of Taiwanese-origin is not subject to this inquiry. However, imports of such merchandise are subject to certification requirements, and cash deposits may be required if the certification requirements are not satisfied. CORE completed in Malaysia from HRS and/or CRS from China also has preliminarily been found to be circumventing the AD/CVD orders on CORE from China and such merchandise is subject to similar certification requirements.[4] Additionally, if an importer imports CORE from Malaysia and claims that the CORE was not produced from HRS and/or CRS substrate manufactured in Taiwan, the importer and exporter are required to meet the certification and documentation requirements described

[1] *See Certain Corrosion-Resistant Steel Flat Products from India, Italy, the People's Republic of China, the Republic of Korea, and Taiwan: Amended Final Affirmative Antidumping Duty Determination for India and Taiwan, and Antidumping Duty Orders,* 81 FR 48390 (July 25, 2016) (*Taiwan CORE Order*).

[2] The notice of initiation was subsequently published in the **Federal Register** on August 21, 2019. *See Corrosion-Resistant Steel Products from Taiwan: Initiation of Anti-Circumvention Inquiry on the Antidumping Duty Order,* 84 FR 43581 (August 21, 2019) (*Initiation Notice*) and accompanying Memorandum, ''Certain Corrosion-Resistant Steel Products from Taiwan: Initiation of Anti-Circumvention Inquiry on the Antidumping Duty Order,'' dated August 12, 2019.

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Anti-Circumvention Inquiry of Certain Corrosion-Resistant Steel Products from Taiwan,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See* **Federal Register** notice, ''*Certain Corrosion-Resistant Steel Products from Taiwan: Affirmative Preliminary Determination of Anti-Circumvention Inquiry on the Antidumping Duty Order,*'' dated concurrently with this notice.

in Appendices II, III and IV, in order for cash deposits pursuant to the *Taiwan CORE Order* not to be required.

In the situation where no certification is provided for an entry, and AD/CVD orders from two countries (China and Taiwan) potentially apply to that entry, Commerce intends to instruct CBP to suspend liquidation of the entry and collect cash deposits at the rates applicable to the *China CORE Orders* [5] (*i.e.,* the AD rate established for the China-wide entity (199.43 percent) and the CVD rate established for all-other Chinese producers/exporters (39.05 percent)).[6] This is to prevent evasion, given that the *CORE China Orders* rates are higher than the AD rate established for CORE from Taiwan. In the situation where a certification is provided for the AD/CVD orders on CORE from China (stating that the merchandise was not produced from HRS and/or CRS from China), but no other certification is provided, then Commerce intends to instruct CBP to suspend the entry and collect cash deposits at the AD all-others rate applicable to the *Taiwan CORE Order* (*i.e.,* 3.66 percent).

Commerce preliminarily determines that the following companies are not eligible for the certification process: Hsin Kuang Steel Co Ltd; FIW Steel Sdn Bhd; NS BlueScope Malaysia Sdn Bhd; and YKGI/Yung Kong Galv. Ind/ Starshine Holdings Sdn Bhd/ASTEEL Sdn Bhd. Additionally, exporters are not eligible to certify shipments of merchandise produced by above-listed companies. Further, imports of CORE from Malaysia that is produced and/or exported by these ineligible companies are similarly ineligible for the certification process with regard to those imports.

Verification

As provided in 19 CFR 351.307, Commerce intends to verify information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last final verification report is issued in this anti-circumvention inquiry, unless the Secretary alters the time limit. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[7] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this anti-circumvention inquiry are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

International Trade Commission Notification

Commerce, consistent with section 781(e) of the Act, has notified the International Trade Commission (ITC) of this preliminary determination to include the merchandise subject to this anti-circumvention inquiry within the *Taiwan CORE Order.* Pursuant to section 781(e) of the Act, the ITC may request consultations concerning Commerce's proposed inclusion of the merchandise subject to this inquiry. If, after consultations, the ITC believes that a significant injury issue is presented by the proposed inclusion, it will have 60 days from the date of notification by Commerce to provide written advice.

Notification to Interested Parties

This determination is issued and published in accordance with section 781(b) of the Act and 19 CFR 351.225(f).

Dated: February 7, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Scope of the Anti-Circumvention Inquiry
V. Period of Inquiry
VI. Statutory Framework
VII. Use of Facts of Available With An Adverse Inference
VIII. Anti-Circumvention Determination
IX. Country-Wide Determination
X. Certification for Not Using Taiwanese-Origin HRS and/or CRS
XI. Verification
XII. Recommendation

Appendix II

Certification Requirements

If an importer imports certain corrosion-resistant steel products (CORE) from Malaysia and claims that the CORE was not produced from hot-rolled steel and/or cold-rolled steel substrate (substrate) manufactured in Taiwan, the importer is required to complete and maintain the importer certification attached hereto as Appendix III and all supporting documentation. Where the importer uses a broker to facilitate the entry process, it should obtain the entry number from the broker. Agents of the importer, such as brokers, however, are not permitted to make this certification on behalf of the importer.

The exporter is required to complete and maintain the exporter certification, attached as Appendix III, and is further required to provide the importer a copy of that certification and all supporting documentation.

For shipments and/or entries on or after August 12, 2019 through March 7, 2020 for which certifications are required, importers and exporters should complete the required certification within 30 days of the publication of this notice in the **Federal Register**. Accordingly, where appropriate, the relevant bullet in the certification should be edited to reflect that the certification was completed within the time frame specified above. For example, the bullet in the importer certification that reads: ''This certification was completed at or prior to the time of Entry,'' could be edited as follows: ''The imports referenced herein entered before March 8, 2020. This certification was completed on mm/dd/yyyy, within 30 days of the **Federal Register** notice publication of the preliminary determination of circumvention.'' Similarly, the bullet in the exporter certification that reads, ''This certification was completed at or prior to the time of shipment,'' could be edited as follows: ''The shipments/products referenced herein shipped before March 8, 2020. This certification was completed on mm/dd/yyyy, within 30 days of the **Federal Register** notice publication of the preliminary determination of circumvention. For such entries/

[5] *See Certain Corrosion-Resistant Steel Flat Products from India, Italy, the People's Republic of China, the Republic of Korea, and Taiwan: Amended Final Affirmative Antidumping Duty Determination for India and Taiwan, and Antidumping Duty Orders,* 81 FR 48390 (July 25, 2016); *see also Certain Corrosion-Resistant Steel Products from India, Italy, Republic of Korea, and the People's Republic of China: Countervailing Duty Order,* 81 FR 48387 (July 25, 2016) (collectively, *China CORE Orders*).

[6] *See China CORE Orders.*

[7] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

shipments, importers and exporters each have the option to complete a blanket certification covering multiple entries/shipments, individual certifications for each entry/shipment, or a combination thereof.

For shipments and/or entries on or after March 8, 2020, for which certifications are required, importers should complete the required certification at or prior to the date of Entry and exporters should complete the required certification and provide it to the importer at or prior to the date of shipment.

The importer and Malaysian exporter are also required to maintain sufficient documentation supporting their certifications. The importer will not be required to submit the certifications or supporting documentation to U.S. Customs and Border Protection (CBP) as part of the entry process at this time. However, the importer and the exporter will be required to present the certifications and supporting documentation, to Commerce and/or CBP, as applicable, upon request by the respective agency. Additionally, the claims made in the certifications and any supporting documentation are subject to verification by Commerce and/or CBP. The importer and exporter are required to maintain the certifications (the importer must retain both certifications) and supporting documentation for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries.

In the situation where no certification is provided for an entry, and AD/CVD orders from two countries (China and Taiwan) potentially apply to that entry, Commerce intends to instruct CBP to suspend the entry and collect cash deposits at the rate applicable to the *China CORE Orders* (*i.e.,* the AD rate established for the China-wide entity (199.43 percent) and the CVD rate established for all-other Chinese producers/exporters (39.05 percent)).[8] In the situation where a certification is provided for the AD/CVD orders on CORE from China (stating that the merchandise was not produced from HRS and/or CRS from China), but no other certification is provided, then Commerce intends to instruct CBP to suspend the entry and collect cash deposits at the AD all-others rate applicable to the AD order on CORE from Taiwan (*i.e.,* 3.66%).

Appendix III

Exporter Certification

I hereby certify that:

- My name is {COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF EXPORTING COMPANY}, located at {ADDRESS OF EXPORTING COMPANY};
- I have direct personal knowledge of the facts regarding the production and exportation of the corrosion resistant steel products identified below. ''Direct personal knowledge'' refers to facts the certifying party is expected to have in its own books and records. For example, an exporter should have direct personal knowledge of the producer's identity and location.
- The corrosion resistant steel products covered by this certification were produced by {NAME OF PRODUCING COMPANY}, located at {ADDRESS OF PRODUCING COMPANY}; *for each additional company, repeat:* {NAME OF PRODUCING COMPANY}, located at {ADDRESS OF PRODUCING COMPANY}
- The corrosion resistant steel products produced in Malaysia were not manufactured using hot-rolled steel and/or cold-rolled steel substrate from Taiwan;
- This certification applies to the following sales:

Producer	Invoice No.	Invoice line item No.

- The corrosion resistant steel products covered by this certification were sold to {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}.
- The corrosion resistant steel products covered by this certification were shipped to {NAME OF PARTY TO WHOM MERCHANDISE WAS SHIPPED}, located at {ADDRESS OF SHIPMENT}.
- I understand that {NAME OF EXPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, mill certificates, production records, invoices, etc.) for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in the United States courts regarding such entries;
- I understand that {NAME OF EXPORTING COMPANY} must provide a copy of this Exporter Certification to the U.S. importer by the time of shipment;
- I understand that {NAME OF EXPORTING COMPANY} is required to provide a copy of this certification and supporting records, upon request, to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce);
- I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce;
- I understand that failure to maintain the required certification, and/or failure to substantiate the claims made herein, and/or failure to allow CBP and/or Commerce to verify the claims made herein, may result in a de facto determination that all sales to which this certification applies are within the scope of the antidumping/countervailing duty order on corrosion resistant steel products from Taiwan. I understand that such finding will result in:
  - Suspension of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met; and
  - the requirement that the importer post applicable antidumping duty and/or countervailing duty cash deposits (as appropriate) equal to the rates as determined by Commerce;
  - the revocation of {NAME OF EXPORTING COMPANY}'s privilege to certify future exports of corrosion resistant steel products from Malaysia as not manufactured using hot-rolled steel and/or cold-rolled steel substrate from Taiwan.
- This certification was completed at or prior to the time of shipment; and
- I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make materially false statements to the U.S. government.

Signature

NAME OF COMPANY OFFICIAL

TITLE

DATE

Importer Certification

I hereby certify that:

- My name is {IMPORTING COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF IMPORTING COMPANY}, located at {ADRESS OF IMPORTING COMPANY}.
- I have direct personal knowledge of the facts regarding the importation into the Customs territory of the United States of the corrosion resistant steel products produced in Malaysia that entered under entry number(s), identified below, and which are covered by this certification. ''Direct personal knowledge'' refers to facts the certifying party is expected to have in its own records. For example, the importer should have direct personal knowledge of the importation of the product (*e.g.,* the name of the exporter) in its records;
- The corrosion resistant steel products covered by this certification were exported by {NAME OF EXPORTING COMPANY}, located at {ADDRESS OF EXPORTING COMPANY}.

If the importer is acting on behalf of the first U.S. customer, complete this paragraph:

- The corrosion resistant steel products

[8] *See China CORE Orders.*

covered by this certification were imported by {NAME OF IMPORTING COMPANY} on behalf of {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}.

- The corrosion resistant steel products covered by this certification were shipped to {NAME OF PARTY TO WHOM MERCHANDISE WAS FIRST SHIPPED IN THE UNITED STATES}, located at {ADDRESS OF SHIPMENT}.
- I have personal knowledge of the facts regarding the production of the corrosion resistant steel products identified below. ''Personal knowledge'' includes facts obtained from another party, (*e.g.,* correspondence received by the importer (or exporter) from the producer regarding the country of manufacture of the imported products);
- The corrosion resistant steel products covered by this certification were produced by {NAME OF PRODUCING COMPANY}, located at {ADDRESS OF PRODUCING COMPANY}; *for each additional company, repeat:* {NAME OF PRODUCING COMPANY}, located at {ADDRESS OF PRODUCING COMPANY}.
- The corrosion resistant steel products covered by this certification were not manufactured using hot-rolled steel and/or cold-rolled steel substrate from Taiwan.
- This certification applies to the following entries:

Producer	Entry summary No.	Entry summary line item No.	Invoice No.	Invoice Line Item No.

- I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, mill certificates, production records, invoices, etc.) for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in the United States courts regarding such entries;
- I understand that {NAME OF IMPORTING COMPANY} is required to provide this certification and supporting records, upon request, to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce);
- I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of the exporter's certification (attesting to the production and/or export of the imported merchandise identified above), and any supporting records provided by the exporter to the importer, for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries;
- I understand that {NAME OF IMPORTING COMPANY}is required to maintain and, upon request, provide a copy of the exporter's certification and any supporting records provided by the exporter to the importer, to CBP and/or Commerce;
- I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce;
- I understand that failure to maintain the required certifications, and/or failure to substantiate the claims made herein, and/or failure to allow CBP and/or Commerce to verify the claims made herein, may result in a de facto determination that all entries to which this certification applies are within the scope of the antidumping/countervailing duty order on corrosion resistant steel products from Taiwan. I understand that such finding will result in:
  - Suspension of liquidation of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met; and;
  - the requirement that the importer post applicable antidumping duty and/or countervailing duty cash deposits (as appropriate) equal to the rates determined by Commerce;

the revocation of {NAME OF IMPORTING COMPANY}'s privilege to certify future imports of corrosion resistant steel products from Malaysia as not manufactured using hot-rolled steel and/or cold-rolled steel substrate from Taiwan.

- I understand that agents of the importer, such as brokers, are not permitted to make this certification;
- This certification was completed at or prior to the time of Entry; and
- I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make materially false statements to the U.S. government.

Signature

NAME OF COMPANY OFFICIAL

TITLE

DATE

[FR Doc. 2020–03138 Filed 2–14–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–887]

Carbon and Alloy Steel Threaded Rod From India: Final Affirmative Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that carbon and alloy steel threaded rod (steel threaded rod) from India is being, or is likely to be, sold in the United States at less than fair value (LTFV).

DATES: Applicable February 18, 2020.

FOR FURTHER INFORMATION CONTACT: Annathea Cook or Jerry Huang, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0250 or (202) 482–4047, respectively.

SUPPLEMENTARY INFORMATION:

Background

On September 25, 2019, Commerce published the *Preliminary Determination* in this LTFV investigation.[1] On January 9, 2020, we issued a Post-Preliminary Determination with respect to the petitioner's particular market situation allegation.[2] We invited interested parties to comment on the *Preliminary Determination* and Post-Preliminary Determination. A summary of the events that occurred since Commerce published the *Preliminary Determination,* as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.[3]

[1] *See Carbon and Alloy Steel Threaded Rod from India: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of provisional Measures,* 84 FR 50376 (September 25, 2019) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Antidumping Duty Investigation of Carbon and Alloy Steel Threaded Rod from India: Decision on Particular Market Situation Allegation,'' dated January 9, 2020 (Post-Preliminary Determination).

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Determination in the Less-Than-Fair-Value Investigation of Carbon and Alloy Steel Threaded Rod from India,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to register users at *http://access.trade.gov,* and to all parties in the Central Records Unit, room B8024 of the main Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be access directly at *http://enforcement.trade.gov.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Period of Investigation

The period of investigation is January 1, 2018 through December 31, 2018.

Scope of the Investigation

The products covered by this investigation are steel threaded rods from India. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

During the course of this investigation and the concurrent countervailing duty (CVD) investigation of steel threaded rod from India, the concurrent antidumping duty (AD) and CVD investigations of steel threaded rod from the People's Republic of China, and the concurrent AD investigations of steel threaded rod from Taiwan and Thailand, certain interested parties commented on the scope of the investigations as it appeared in the *Initiation Notices.*[4]

On July 22, 2019, we issued a Preliminary Scope Memorandum.[5] Interested parties' scope-related case briefs were due on August 28, 2019.[6] Because we did not receive any comments on the Preliminary Scope Memorandum, we are adopting the proposed scope language in this final determination, *see* Appendix I.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs submitted by interested parties in this investigation are addressed in the Issues and Decision Memorandum. For a list of these issues, *see* Appendix II.

Verification

Between October and December 2019, we conducted verification of the sales and cost of production data reported by the participating respondent in this investigation, Mangal Steel Enterprises (Mangal), as well as the sales data reported by Mangal's U.S. affiliate, North American Steel Connection, in accordance with section 783(i) of Tariff Act of 1930, as amended (the Act).[7]

Changes Since the Preliminary Determination

Based on our analysis of the comments received and our findings at verification, we made certain changes to the margin calculations for Mangal since the *Preliminary Determination.* For a discussion of these changes, *see* the Issues and Decision Memorandum.

Additionally, for purposes of this final determination, Commerce determined Daksh Fasteners' margin on the basis of adverse facts available (AFA), pursuant to sections 776(a)(2)(A)–(C) and 776(b) of the Act. For further information, *see* the Issues and Decision Memorandum.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated weighted-average dumping margin for all other producers and exporters not individually investigated shall be equal to the weighted average of the estimated weighted-average dumping margins established for individually investigated exporters and producers, excluding any margins that are zero, *de minimis,* or determined entirely under section 776 of the Act. Because the final rate determined for Daksh Fasteners is based entirely on AFA, we based the all-others rate on the rate calculated for Mangal.

Final Determination

Commerce determines that the weighted-average dumping margins are as follows:

Exporter/producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for export subsidy offset(s))[8] (percent)
Daksh Fasteners[9]	28.34	22.86
Mangal Steel Enterprise Limited	2.47	0.00
All Others	2.47	0.00

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all appropriate entries of steel threaded rod from India, as described in Appendix I of this notice, which are entered or withdrawn from warehouse for consumption on or after September 25, 2019, the date of

[4] *See Carbon and Alloy Steel Threaded Rod from India, Taiwan, Thailand, and the People's Republic of China: Initiation of Less-Than-Fair-Value Investigations,* 84 FR 10034 (March 19, 2019); *Carbon and Alloy Steel Threaded Rod from India and the People's Republic of China: Initiation of Countervailing Duty Investigations,* 84 FR 10040 (March 19, 2019) (collectively, *Initiation Notices*).

[5] *See* Memorandum, ''Carbon and Alloy Steel Threaded Rod from India, Taiwan, Thailand, and the People's Republic of China: Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated July 22, 2019.

[6] *See* Preliminary Scope Decision Memorandum at 3.

[7] *See* Memorandum, ''Verification of Cost Response of Mangal Steel Enterprises Ltd. in the Antidumping Duty Investigation of Carbon and Alloy Steel Threaded Rod from India,'' dated December 10, 2019; Memorandum, ''Verification of the Sales Response of Mangal Steel Enterprise Limited in the Antidumping Duty Investigation of Carbon and Alloy Steel Threaded Rod from India,'' dated January 3, 2020; and Memorandum, ''Verification of the Constructed Export Price (CEP) Sales Response of North American Steel Connection in the Antidumping Duty Investigation of Carbon and Alloy Steel Threaded Rod from India,'' dated January 3, 2020.

[8] As noted in the ''Continuation of Suspension of Liquidation'' section, we are adjusting the cash deposit rates to take into account the export subsidy rates found in the companion CVD investigation. Specifically, for Mangal and all others, we adjusted the cash deposit rates by the export contingent subsidy rate calculated for Mangal in that investigation (*i.e.,* 5.48 percent). We also adjusted the cash deposit rate for Daksh Fasteners by the export contingent subsidy rate for Mangal, because it is the lowest export subsidy rate determined for any party in the companion CVD proceeding.

[9] As explained in the Issues and Decision Memorandum, this company is receiving a rate based on total AFA because it did not respond to our AD questionnaire.

publication in the **Federal Register** of the affirmative *Preliminary Determination.*

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), we will instruct CBP to require a cash deposit for entries of subject merchandise equal to the estimated weighted-average dumping margin as follows: (1) The cash deposit rate for the respondents listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this final determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin, *i.e.,* 2.47 percent. These suspension of liquidation instructions will remain in effect until further notice.

In the event that a CVD order is issued, and suspension of liquidation is resumed in the companion CVD investigation on steel threaded rod from India, Commerce will instruct CBP to require cash deposits adjusted by the amount of export subsidies, as appropriate. These adjustments are reflected in the final column of the rate chart above. Until such suspension of liquidation is resumed in the companion CVD investigation, and so long as suspension of liquidation continues under this AD investigation, the cash deposit rates for this AD investigation will be the rates identified in the estimated weighted-average dumping margin column in the rate chart above.

Disclosure

Commerce will disclose to interested parties the calculations performed in connection with a final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final determination in the **Federal Register**, in accordance with 19 CFR 351.224(b).

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the U.S. International Trade Commission (ITC) of the final affirmative determination of sales at LTFV. Because the final determination in this proceeding is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of steel threaded rod from India no later than 45 days after this final determination. If the ITC determines that material injury, or threat of material injury, does not exist, the proceeding will be terminated, and all cash deposits will be refunded. If the ITC determines that such injury does exist, Commerce will issue an AD duty order directing CBP to assess, upon further instruction by Commerce, AD duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Notification Regarding Administrative Protective Order

This notice serves as a reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination is issued and published in accordance with sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: February 7, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by the scope of this investigation is carbon and alloy steel threaded rod. Steel threaded rod is certain threaded rod, bar, or studs, of carbon or alloy steel, having a solid, circular cross section of any diameter, in any straight length. Steel threaded rod is normally drawn, cold-rolled, threaded, and straightened, or it may be hot-rolled. In addition, the steel threaded rod, bar, or studs subject to these investigations are non-headed and threaded along greater than 25 percent of their total actual length. A variety of finishes or coatings, such as plain oil finish as a temporary rust protectant, zinc coating (*i.e.,* galvanized, whether by electroplating or hot-dipping), paint, and other similar finishes and coatings, may be applied to the merchandise.

Steel threaded rod is normally produced to American Society for Testing and Materials (ASTM) specifications ASTM A36, ASTM A193 B7/B7m, ASTM A193 B16, ASTM A307, ASTM A320 L7/L7M, ASTM A320 L43, ASTM A354 BC and BD, ASTM A449, ASTM F1554–36, ASTM F1554–55, ASTM F1554 Grade 105, American Society of Mechanical Engineers (ASME) specification ASME B18.31.3, and American Petroleum Institute (API) specification API 20E. All steel threaded rod meeting the physical description set forth above is covered by the scope of these investigations, whether or not produced according to a particular standard.

Subject merchandise includes material matching the above description that has been finished, assembled, or packaged in a third country, including by cutting, chamfering, coating, or painting the threaded rod, by attaching the threaded rod to, or packaging it with, another product, or any other finishing, assembly, or packaging operation that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the threaded rod.

Carbon and alloy steel threaded rod are also included in the scope of the investigation whether or not imported attached to, or in conjunction with, other parts and accessories such as nuts and washers. If carbon and alloy steel threaded rod are imported attached to, or in conjunction with, such non-subject merchandise, only the threaded rod is included in the scope.

Excluded from the scope of the investigation are: (1) Threaded rod, bar, or studs which are threaded only on one or both ends and the threading covers 25 percent or less of the total actual length; and (2) stainless steel threaded rod, defined as steel threaded rod containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with our without other elements.

Specifically excluded from the scope of the investigation is threaded rod that is imported as part of a package of hardware in conjunction with a ready-to-assemble piece of furniture. Steel threaded rod is currently classifiable under subheadings 7318.15.5051, 7318.15.5056, and 7318.15.5090 of the Harmonized Tariff Schedule of the United States (HTSUS). Subject merchandise may also enter under subheading 7318.15.2095 and 7318.19.0000 of the HTSUS. The HTSUS subheadings are provided for convenience and U.S. Customs purposes only. The written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Investigation
IV. Margin Calculations
V. Discussion of the Issues
  Comment 1: Calculation of Constructed Value Profit and Selling Expense Ratios
  Comment 2: Excluded Electricity Costs
  Comment 3: Mangal Steel Enterprise's General and Administrative Expenses
  Comment 4: Adverse Facts Available for Daksh Fasteners
VI. Recommendation

[FR Doc. 2020–03049 Filed 2–14–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–104]

Alloy and Certain Carbon Steel Threaded Rod From the People's Republic of China: Final Affirmative Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that imports of alloy and certain carbon steel threaded rod (threaded rod) from the People's Republic of China (China) are being, or are likely to be, sold in the United States at less than fair value (LTFV). The final dumping margins of sales at LTFV are listed in the ''Final Determination'' section of this notice.

DATES: Applicable February 18, 2020.

FOR FURTHER INFORMATION CONTACT: Yang Jin Chun, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5760.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Determination* in the LTFV investigation of threaded rod from China on September 25, 2019.[1] For a complete description of the events that followed the *Preliminary Determination, see* the Issues and Decision Memorandum.[2]

Period of Investigation

The period of investigation is July 1, 2018 through December 31, 2018.

Scope of the Investigation

The product covered by this investigation is threaded rod from China. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

On July 22, 2019, we issued a Preliminary Scope Memorandum.[3] The scope case briefs were due on August 28, 2019.[4] We received no scope case briefs from interested parties. Therefore, Commerce has made no changes to the scope of this investigation since the *Preliminary Determination.*

Verification

As provided in section 782(i) of the Tariff Act of 1930, as amended (the Act), we verified the U.S. sales and factors of production information submitted by Ningbo Zhongjiang High Strength Bolts Co., Ltd. (Zhongjiang)[5] and Zhejiang Junyue Standard Part Co., Ltd. (Junyue)[6] in November 2019. We used standard verification procedures, including an examination of relevant accounting and production records, and original source documents provided by these two respondents.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs that were submitted by parties in this investigation are addressed in the Issues and Decision Memorandum. For a list of the issues raised by interested parties and addressed in the Issues and Decision Memorandum, *see* Appendix II to this notice. The Issues and Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

China-Wide Entity and Use of Adverse Facts Available (AFA)

We continue to find that the use of facts available is warranted in determining the rate of the China-wide entity pursuant to sections 776(a)(1) and (a)(2)(A)–(C) of the Act.[7] Further, use of AFA is warranted because the China-wide entity did not cooperate to the best of its ability to comply with our requests for information and, accordingly, we applied adverse inferences in selecting from the facts available, pursuant to section 776(b) of the Act and 19 CFR 351.308(a).

Changes From the Preliminary Determination

Based on our analysis of the comments received and our findings at verification, we made certain changes to the dumping margin calculations for Junyue and Zhongjiang.[8] Consistent with our *Preliminary Determination,* as AFA, we continued to rely on the highest petition rate of 59.45 percent to determine the China-wide entity's dumping margin.[9]

Combination Rates

Consistent with the *Preliminary Determination*[10] and Policy Bulletin 05.1,[11] Commerce calculated combination rates for the respondents that are eligible for a separate rate in this investigation.

Final Determination

Commerce determines that the following weighted-average dumping margins exist:

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[1] *See Alloy and Certain Carbon Steel Threaded Rod from the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination and Extension of Provisional Measures,* 84 FR 50379 (September 25, 2019) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Alloy and Certain Carbon Steel Threaded Rod from the People's Republic of China: Issues and Decision Memorandum for the Final Affirmative Determination of Sales at Less Than Fair Value,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Memorandum, ''Carbon and Alloy Steel Threaded Rod from India, Taiwan, Thailand, and the People's Republic of China: Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated July 22, 2019 (Preliminary Scope Decision Memorandum).

[4] The scope case briefs were due 30 days after the publication of *Carbon and Alloy Steel Threaded Rod from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination with Final Antidumping Duty Determination,* 84 FR 36578 (July 29, 2019). *See* Preliminary Scope Decision Memorandum at 3.

[5] *See* Memorandum, ''Verification of the Questionnaire Responses of Ningbo Zhongjiang High Strength Bolts Co., Ltd. in the Antidumping Investigation of Alloy and Certain Carbon Steel Threaded Rod from the People's Republic of China,'' dated December 3, 2019.

[6] *See* Memorandum, ''Verification of the Questionnaire Responses of Zhejiang Junyue Standard Part Co., Ltd. in the Antidumping Investigation of Alloy and Certain Steel Threaded Rod from the People's Republic of China,'' dated December 3, 2019.

[7] *See Preliminary Determination* PDM at 16–18.

[8] *See* the Issues and Decision Memorandum for a discussion of these changes.

[9] *Id.* at 3–4 for a full discussion of this issue.

[10] *See Preliminary Determination.*

[11] *See* Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, ''Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries,'' dated April 5, 2005 (Policy Bulletin 05.1), available on Commerce's website at *http://enforcement.trade.gov/policy/bull05-1.pdf.*

Exporter	Producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Ningbo Zhongjiang High Strength Bolts Co., Ltd	Ningbo Zhongjiang High Strength Bolts Co., Ltd	14.16	3.62
Zhejiang Junyue Standard Part Co., Ltd	Zhejiang Junyue Standard Part Co., Ltd	4.26	0.00
Cooper & Turner (Ningbo) International Trading Co., Ltd.	Zhejiang Cooper & Turner Fasteners Co., Ltd	11.47	0.00
Cooper & Turner (Ningbo) International Trading Co., Ltd.	Zhejiang Morgan Brother Technology Co., Ltd	11.47	0.00
Cooper & Turner (Ningbo) International Trading Co., Ltd.	Zhejiang Huiyou Import & Export Co., Ltd	11.47	0.00
EC International (Nantong) Co., Ltd	Ningbo Zhongjiang High Strength Bolts Co., Ltd	11.47	0.00
EC International (Nantong) Co., Ltd	Ningbo Zhenghai Yongding Fasteners Manufacture Co., Ltd.	11.47	0.00
EC International (Nantong) Co., Ltd	Zhejiang Junyue Standard Part Co., Ltd	11.47	0.00
EC International (Nantong) Co., Ltd	Haiyan Qinshan Rubber Factory	11.47	0.00
IFI & Morgan Ltd	Zhejiang Morgan Brother Technology Co., Ltd	11.47	0.00
Jiaxing Genteel Import & Export Co., Ltd	Ningbo Zhenhai Zhongbiao Standard Parts Factory.	11.47	0.00
Ningbo Dingtuo Imp. & Exp. Co., Ltd	Ningbo Jinding Fastening Piece Co., Ltd	11.47	0.00
Zhejiang Heiter Mfg & Trade Co., Ltd	Zhejiang Golden Automotive Fastener Co., Ltd	11.47	0.00
Ningbo Jinding Fastening Piece Co., Ltd	Ningbo Jinding Fastening Piece Co., Ltd	11.47	0.00
Ningbo Qunli Fastener Manufacture Co., Ltd	Ningbo Qunli Fastener Manufacture Co., Ltd	11.47	0.00
Nantong Runyou Metal Products Co., Ltd	Nantong Runyou Metal Products Co., Ltd	11.47	0.00
Ningbo Shareway Import & Export, Co., Ltd	Zhejiang Junyue Standard Parts Co., Ltd	11.47	0.00
Ningbo Xingsheng Oil Pipe Fittings Manufacture Co., Ltd.	Ningbo Xingsheng Oil Pipe Fittings Manufacture Co., Ltd.	11.47	0.00
Ningbo Zhenghai Yongding Fastener Co., Ltd	Ningbo Zhenghai Yongding Fastener Co., Ltd	11.47	0.00
RMB Fasteners Ltd	Zhejiang Morgan Brother Technology Co., Ltd	11.47	0.00
Zhejiang Morgan Brother Technology Co., Ltd	Zhejiang Morgan Brother Technology Co., Ltd	11.47	0.00
China-Wide Entity [12]		59.45	48.91

Disclosure

We intend to disclose the calculations performed to parties in this proceeding within five days after public announcement of the final determination in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

In accordance with sections 735(c)(1)(B) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all entries of threaded rod from China, as described in Appendix I of this notice, which were entered or withdrawn from warehouse for consumption on or after September 25, 2019, the date of publication of the *Preliminary Determination* of this investigation in the **Federal Register**.

Pursuant to section 735(c)(1)(B)(ii) of the Act, upon the publication of this notice, Commerce will instruct CBP to require a cash deposit equal to the weighted-average amount by which the normal value exceeds U.S. price as follows: (1) The cash deposit rate for the exporter/producer combinations listed in the table above will be the rate identified in the table; (2) for all combinations of Chinese exporters/producers of subject merchandise that have not received their own separate rate above, the cash-deposit rate will be the cash deposit rate established for the China-wide entity; and (3) for all non-Chinese exporters of subject merchandise which have not received their own separate rate above, the cash-deposit rate will be the cash deposit rate applicable to the Chinese exporter/producer combination that supplied that non-Chinese exporter. These suspension of liquidation instructions will remain in effect until further notice.

To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of domestic subsidy pass-through and export subsidies determined in a companion countervailing duty (CVD) proceeding when CVD provisional measures are in effect. Accordingly, where Commerce makes an affirmative determination for domestic subsidy pass-through or export subsidies, Commerce offsets the calculated estimated weighted-average dumping margin by the appropriate rate(s). In this case, we have made a negative determination for domestic subsidy pass-through for all respondents, but we have also found export subsidies for all respondents. In particular, Commerce issued the final determination of the concurrent CVD investigation of threaded rod from China, in which it found export-contingent subsidies of 10.54 percent for Zhongjiang and 31.62 percent for Junyue.[13] Therefore, we deducted export subsidies from the final margins and adjusted the cash deposit rates.[14] However, suspension of liquidation for provisional measures in the companion CVD case has been discontinued;[15] therefore, we are not instructing CBP to collect cash deposits based upon the adjusted estimated weighted-average dumping margin for those export subsidies at this time.

[12] Commerce preliminarily denied the separate rate eligibility for Jiaxing Xingcheng Electronics Co., Ltd., Ningbo Panxiang Imp & Exp Co., Ltd., Ningbo Zhonglian Fastener Co., Ltd., and Ningbo Zhong Xin Angora Spinning Mill. *See Preliminary Determination,* 84 FR at 50380, n. 12. For the final determination, Commerce continues to deny their separate rate eligibility and treat them as part of the China-wide entity.

[13] *See* the unpublished **Federal Register** notice entitled ''Carbon and Alloy Steel Threaded Rod from the People's Republic of China: Final Affirmative Countervailing Duty Determination,'' dated concurrently with this notice.

[14] *See* Memorandum, ''Alloy and Certain Carbon Steel Threaded Rod from the People's Republic of China: Final Separate Rate for Non-Selected Respondents,'' dated concurrently with this notice for the cash deposit rate adjustment for non-selected separate rate respondents.

[15] *See* CBP Message No. 9331312 dated November 27, 2019, available at *https://aceservices.cbp.dhs.gov/adcvdweb/ad_cvd_msgs/27895.*

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the International Trade Commission (ITC) of our final affirmative determination of sales at LTFV. Because the final determination in this proceeding is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of subject merchandise from China no later than 45 days after our final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated and all cash deposits posted will be refunded or canceled. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Notification Regarding Administrative Protective Order

This notice will serve as a reminder to the parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination is issued and published in accordance with sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: February 7, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by the scope of this investigation is alloy and certain carbon steel threaded rod. Alloy and certain carbon steel threaded rod are certain threaded rod, bar, or studs, of carbon or alloy steel, having a solid, circular cross section of any diameter, in any straight length. Alloy and certain carbon steel threaded rod are normally drawn, cold-rolled, threaded, and straightened, or it may be hot-rolled. In addition, the alloy and certain carbon steel threaded rod, bar, or studs subject to this investigation are non-headed and threaded along greater than 25 percent of their total actual length. A variety of finishes or coatings, such as plain oil finish as a temporary rust protectant, zinc coating (*i.e.,* galvanized, whether by electroplating or hot-dipping), paint, and other similar finishes and coatings, may be applied to the merchandise. Alloy Steel threaded rod is normally produced to American Society for Testing and Materials (ASTM) specifications A193 B7/B7m, A193 B16, A320 L7/L7m, A320 L43, A354 BC and BD, and F1554 Grade 105. Other specifications are Society of Automotive Engineers (SAE) specification 1429 grades 5 and 8, International Organization for Standardization (ISO) specification 898 class 8.8 and 10.9, and American Petroleum Institute (API) specification 20E. Certain carbon steel threaded rod is normally produced to ASTM specification A449. All steel threaded rod meeting the physical description set forth above is covered by the scope of this investigation, whether or not produced according to a particular standard.

Subject merchandise includes material matching the above description that has been finished, assembled, or packaged in a third country, including by cutting, chamfering, coating, or painting the threaded rod, by attaching the threaded rod to, or packaging it with, another product, or any other finishing, assembly, or packaging operation that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the threaded rod.

Alloy and certain carbon steel threaded rod are also included in the scope of this investigation whether or not imported attached to, or in conjunction with, other parts and accessories such as nuts and washers. If carbon and alloy steel threaded rod are imported attached to, or in conjunction with, such non-subject merchandise, only the threaded rod is included in the scope. Excluded from the scope of this investigation are: (1) Threaded rod, bar, or studs which are threaded only on one or both ends and the threading covers 25 percent or less of the total actual length; and (2) stainless steel threaded rod, defined as steel threaded rod containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements.

Excluded from the scope of the antidumping investigation on steel threaded rod from the People's Republic of China is any merchandise covered by the existing antidumping order on Certain Steel Threaded Rod from the People's Republic of China. *See Certain Steel Threaded Rod from the People's Republic of China: Notice of Antidumping Duty Order,* 74 FR 17154 (April 14, 2009).

Specifically excluded from the scope of this investigation is threaded rod that is imported as part of a package of hardware in conjunction with a ready-to-assemble piece of furniture. Alloy and certain carbon steel threaded rod are currently classifiable under subheadings 7318.15.5051, 7318.15.5056, and 7318.15.5090 of the Harmonized Tariff Schedule of the United States (HTSUS). Subject merchandise may also enter under subheading 7318.15.2095 and 7318.19.0000 of the HTSUS. The HTSUS subheadings are provided for convenience and U.S. Customs purposes only. The written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Surrogate Country
IV. Separate Rates
V. China-Wide Rate
VI. Adjustments to Cash Deposit Rates
VII. Changes Since the Preliminary Determination
VIII. Discussion of the Issues
  Comment 1: Double Remedies
  Comment 2: Export Subsidies
  Comment 3: Alloy Wire Rod
  Comment 4: Zinc Powder
  Comment 5: Selection of Primary Surrogate Country
  Comment 6: Labor
  Comment 7: SermaGard
  Comment 8: Octyl Phenol and Ethylene Oxide Emulsifier
  Comment 9: Surrogate Financial Ratios
  Comment 10: Junyue's Factors of Production
  Comment 11: Ocean Freight
  Comment 12: Surrogate Movement Expenses on a Gross Weight Basis
  Comment 13: Zhongjiang's U.S. Inland Freight from Port to Customer
  Comment 14: Differential Pricing
  Comment 15: Irrecoverable Value-Added Tax
IX. Recommendation

[FR Doc. 2020–03048 Filed 2–14–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–026; C–570–027]

Certain Corrosion-Resistant Steel Products From the People's Republic of China: Affirmative Preliminary Determination of Circumvention Involving Malaysia

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that imports of certain corrosion-resistant steel products (CORE), completed in Malaysia using hot-rolled steel (HRS) and/or cold-rolled steel (CRS) flat products manufactured in the People's Republic of China (China), are circumventing the antidumping duty (AD) and countervailing duty (CVD) orders on CORE from China.

DATES: Applicable February 18, 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 Avenue NW, Washington, DC 20230; telephone: (202) 482–6386.

SUPPLEMENTARY INFORMATION:

Background

On August 12, 2019, Commerce self-initiated country-wide anti-circumvention inquiries of the *China CORE Orders* [1] covering Chinese-origin HRS and/or CRS exported to various countries, including Malaysia, for completion into CORE and subsequently exported to the United States.[2] In the *Initiation Notice,* Commerce initiated the instant anti-circumvention inquiries based on available information and an analysis pursuant to section 781(b) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.225(h), to determine whether the importation of the Chinese-origin HRS or CRS substrate for completion into CORE in Malaysia and subsequent exportation of that CORE to the United States constitutes circumvention of the *China CORE Orders.*

For a complete description of the record developed since the initiation of these inquiries, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Orders

The products covered by these orders are certain flat-rolled steel products, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel- or iron-based alloys, whether or not corrugated or painted, varnished, laminated, or coated with plastics or other non-metallic substances in addition to the metallic coating. For a complete description of the scope of the orders, *see* the Preliminary Decision Memorandum.

Scope of the Anti-Circumvention Inquiries

These anti-circumvention inquiries cover CORE completed in Malaysia from HRS or CRS substrate input manufactured in China and subsequently exported from Malaysia to the United States (merchandise subject to these inquiries).

Methodology

Commerce is conducting these anti-circumvention inquiries in accordance with section 781(b) of the Act. Because certain interested parties did not cooperate to the best of their abilities in responding to Commerce's requests for information, we have based parts of our preliminary determination on the facts available, with adverse inferences, pursuant to sections 776(a) and (b) of the Act. For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

Preliminary Finding

As detailed in the Preliminary Decision Memorandum, we preliminarily determine that CORE completed in Malaysia from HRS and/or CRS substrate sourced from China is circumventing the *China CORE Orders.* We therefore preliminarily determine that it is appropriate to include this merchandise within the *China CORE Orders* and to instruct U.S. Customs and Border Protection (CBP) to suspend liquidation of any entries of CORE from Malaysia produced from HRS and/or CRS from China.

Suspension of Liquidation

As stated above, Commerce has made a preliminary affirmative determination that imports of CORE completed in Malaysia, using HRS and/or CRS flat products manufactured in China, are circumventing the *China CORE Orders.* In accordance with 19 CFR 351.225(1)(2), Commerce will direct CBP to suspend liquidation and to require a cash deposit of estimated duties on unliquidated entries of CORE produced in Malaysia, as appropriate, that were entered, or withdrawn from warehouse, for consumption on or after August 12, 2019, the date of initiation of the anti-circumvention inquiries. The suspension of liquidation instructions will remain in effect until further notice.

CORE produced in Malaysia from HRS and/or CRS that is not of Chinese origin is not subject to these inquiries. However, imports of such merchandise are subject to certification requirements, and cash deposits may be required if the certification requirements are not satisfied. Additionally, CORE completed in Malaysia from HRS and/or CRS from Taiwan also has preliminarily been found to be circumventing the AD order on CORE from Taiwan and such merchandise is subject to similar certification requirements.[4] Accordingly, if an importer imports CORE from Malaysia and claims that the CORE was not produced from HRS and/or CRS substrate manufactured in China, the importer and exporter are required to meet the certification and documentation requirements described in Appendices II, III and IV, in order for cash deposits pursuant to the *China CORE Orders* not to be required.

In the situation where no certification is provided for an entry, and AD/CVD orders from two countries (China and Taiwan) potentially apply to that entry, Commerce intends to instruct CBP to suspend liquidation of the entry and collect cash deposits at the rates applicable to the *China CORE Orders* (*i.e.,* the AD rate established for the China-wide entity (199.43 percent) and the CVD rate established for all-other Chinese producers/exporters (39.05 percent)).[5] This is to prevent evasion, given that the rates applicable to the AD/CVD orders on CORE from China [6] are higher than the AD rate established for CORE from Taiwan. In the situation where a certification is provided for the

[1] *See Certain Corrosion-Resistant Steel Flat Products from India, Italy, the People's Republic of China, the Republic of Korea, and Taiwan: Amended Final Affirmative Antidumping Duty Determination for India and Taiwan, and Antidumping Duty Orders,* 81 FR 48390 (July 25, 2016); *see also Certain Corrosion-Resistant Steel Products from India, Italy, Republic of Korea, and the People's Republic of China: Countervailing Duty Order,* 81 FR 48387 (July 25, 2016) (collectively, *China CORE Orders*).

[2] The notice of initiation subsequently published in the **Federal Register** on August 21, 2019. *See Corrosion-Resistant Steel Products from the People's Republic of China: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders,* 84 FR 43585 (August 21, 2019) (*Initiation Notice*) and accompanying Memorandum, ''Certain Corrosion-Resistant Steel Products from the People's Republic of China: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders,'' dated August 12, 2019.

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Anti-Circumvention Inquiry of Certain Corrosion-Resistant Steel Products from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See* **Federal Register** notice, ''*Certain Corrosion-Resistant Steel Products from Taiwan: Affirmative Preliminary Determination of Anti-Circumvention Inquiry on the Antidumping Duty Order,*'' dated concurrently with this notice.

[5] *See China CORE Orders.*

[6] *Id.*

AD/CVD orders on CORE from China (stating that the merchandise was not produced from HRS and/or CRS from China), but no other certification is provided, then Commerce intends to instruct CBP to suspend the entry and collect cash deposits at the AD all-others rate applicable to the AD order on CORE from Taiwan (*i.e.,* 3.66 percent).

Commerce preliminarily determines that the following companies are not eligible for the certification process: FIW Steel Sdn Bhd; Hsin Kuang Steel Co Ltd; Nippon EGalv Steel Sdn Bhd; NS BlueScope Malaysia Sdn Bhd; and YKGI/Yun Kong Galv. Ind/Starshine Holdings Sdn Bhd./ASTEEL Sdn Bhd. Additionally, exporters are not eligible to certify shipments of merchandise produced by the above-listed companies. Further, importers of CORE from Malaysia that is produced and/or exported by these ineligible companies are similarly ineligible for the certification process with regard to those imports.

Verification

As provided in 19 CFR 351.307, Commerce intends to verify information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last final verification report is issued in these anti-circumvention inquiries, unless the Secretary alters the time limit. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[7] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in these anti-circumvention inquiries are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

International Trade Commission Notification

Commerce, consistent with section 781(e) of the Act, has notified the U.S. International Trade Commission (ITC) of this preliminary determination to include the merchandise subject to these anticircumvention inquiries within the *China CORE Orders.* Pursuant to section 781(e) of the Act, the ITC may request consultations concerning Commerce's proposed inclusion of the merchandise subject to these inquiries. If, after consultations, the ITC believes that a significant injury issue is presented by the proposed inclusion, it will have 60 days from the date of notification by Commerce to provide written advice.

Notification to Interested Parties

This determination is issued and published in accordance with section 781(b) of the Act and 19 CFR 351.225(f).

Dated: February 7, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Orders
IV. Scope of the Anti-Circumvention Inquiries
V. Period of Inquiries
VI. Statutory Framework
VII. Use of Facts Available with an Adverse Inference
VIII. Anti-Circumvention Determination
IX. Country-Wide Determination
X. Certification for Not Using Chinese-Origin HRS and/or CRS
XI. Verification
XII. Recommendation

Appendix II—Certification Requirements

If an importer imports certain corrosion-resistant steel products (CORE) from Malaysia and claims that the CORE was not produced from hot-rolled steel and/or cold-rolled steel substrate (substrate) manufactured in the People's Republic of China (China), the importer is required to complete and maintain the importer certification attached hereto as Appendix III and all supporting documentation. Where the importer uses a broker to facilitate the entry process, it should obtain the entry number from the broker. Agents of the importer, such as brokers, however, are not permitted to make this certification on behalf of the importer.

The exporter is required to complete and maintain the exporter certification, attached as Appendix III, and is further required to provide the importer a copy of that certification and all supporting documentation.

For shipments and/or entries on or after August 12, 2019 through March 7, 2020, for which certifications are required, importers and exporters should complete the required certification within 30 days of the publication of this notice in the **Federal Register**. Accordingly, where appropriate, the relevant bullet in the certification should be edited to reflect that the certification was completed within the time frame specified above. For example, the bullet in the importer certification that reads: ''This certification was completed at or prior to the time of Entry,'' could be edited as follows: ''The imports referenced herein entered before March 8, 2020. This certification was completed on mm/dd/yyyy, within 30 days of the **Federal Register** notice publication of the preliminary determination of circumvention.'' Similarly, the bullet in the exporter certification that reads, ''This certification was completed at or prior to the time of shipment,'' could be edited as follows: ''The shipments/products referenced herein shipped before March 8, 2020. This certification was completed on mm/dd/yyyy, within 30 days of the **Federal Register** notice publication of the preliminary determination of circumvention. For such entries/shipments, importers and exporters each have the option to complete a blanket certification covering multiple entries/shipments, individual certifications for each entry/shipment, or a combination thereof.

For shipments and/or entries on or after March 8, 2020, for which certifications are required, importers should complete the required certification at or prior to the date of Entry and exporters should complete the required certification and provide it to the importer at or prior to the date of shipment.

The importer and Malaysian exporter are also required to maintain sufficient documentation supporting their certifications. The importer will not be required to submit the certifications or supporting documentation to U.S. Customs and Border Protection (CBP) as part of the entry process at this time. However, the importer and the exporter will be required to present the certifications and supporting documentation, to Commerce and/or CBP, as applicable, upon request by the respective agency. Additionally, the claims made in the certifications and any supporting documentation are subject to verification by Commerce and/or CBP. The importer and exporter are required to maintain the certifications (the importer must retain both certifications) and supporting documentation for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries.

[7] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

In the situation where no certification is provided for an entry, and AD/CVD orders from two countries (China and Taiwan) potentially apply to that entry, Commerce intends to instruct CBP to suspend the entry and collect cash deposits at the rate applicable to the *China CORE Orders* (*i.e.,* the AD rate established for the China-wide entity (199.43 percent) and the CVD rate established for all-other Chinese producers/exporters (39.05 percent)). In the situation where a certification is provided for the AD/CVD orders on CORE from China (stating that the merchandise was not produced from HRS and/or CRS from China), but no other certification is provided, then Commerce intends to instruct CBP to suspend the entry and collect cash deposits at the AD all-others rate applicable to the AD order on CORE from Taiwan (*i.e.,* 3.66%).

Appendix III—Exporter Certification

I hereby certify that:

• My name is {COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF EXPORTING COMPANY}, located at {ADDRESS OF EXPORTING COMPANY};

• I have direct personal knowledge of the facts regarding the production and exportation of the corrosion resistant steel products identified below. ''Direct personal knowledge'' refers to facts the certifying party is expected to have in its own books and records. For example, an exporter should have direct personal knowledge of the producer's identity and location.

• The corrosion resistant steel products covered by this certification were produced by {NAME OF PRODUCING COMPANY}, located at {{ADDRESS OF PRODUCING COMPANY}; *for each additional company, repeat:* {NAME OF PRODUCING COMPANY}, located at {ADDRESS OF PRODUCING COMPANY}

• The corrosion resistant steel products produced in Malaysia were not manufactured using hot-rolled steel and/or cold-rolled steel substrate from China;

• This certification applies to the following sales:

Producer	Invoice No.	Invoice line item No.

• The corrosion resistant steel products covered by this certification were sold to {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}.

• The corrosion resistant steel products covered by this certification were shipped to {NAME OF PARTY TO WHOM MERCHANDISE WAS SHIPPED}, located at {ADDRESS OF SHIPMENT}.

• I understand that {NAME OF EXPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, mill certificates, production records, invoices, etc.) for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in the United States courts regarding such entries;

• I understand that {NAME OF EXPORTING COMPANY} must provide a copy of this Exporter Certification to the U.S. importer by the time of shipment;

• I understand that {NAME OF EXPORTING COMPANY} is required to provide a copy of this certification and supporting records, upon request, to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce);

• I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce;

• I understand that failure to maintain the required certification, and/or failure to substantiate the claims made herein, and/or failure to allow CBP and/or Commerce to verify the claims made herein, may result in a de facto determination that all sales to which this certification applies are within the scope of the antidumping/countervailing duty order on corrosion resistant steel products from China. I understand that such finding will result in:

○ Suspension of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met; and

○ the requirement that the importer post applicable antidumping duty and/or countervailing duty cash deposits (as appropriate) equal to the rates as determined by Commerce;

○ the revocation of {NAME OF EXPORTING COMPANY}'s privilege to certify future exports of corrosion resistant steel products from Malaysia as not manufactured using hot-rolled steel and/or cold-rolled steel substrate from China.

• This certification was completed at or prior to the time of shipment; and

• I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make materially false statements to the U.S. government.

Signature

NAME OF COMPANY OFFICIAL
TITLE
DATE

Appendix IV—Importer Certification

I hereby certify that:

• My name is {IMPORTING COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF IMPORTING COMPANY}, located at {ADRESS OF IMPORTING COMPANY}.

• I have direct personal knowledge of the facts regarding the importation into the Customs territory of the United States of the corrosion resistant steel products produced in Malaysia that entered under entry number(s), identified below, and which are covered by this certification. ''Direct personal knowledge'' refers to facts the certifying party is expected to have in its own records. For example, the importer should have direct personal knowledge of the importation of the product (*e.g.,* the name of the exporter) in its records;

• The corrosion resistant steel products covered by this certification were exported by {NAME OF EXPORTING COMPANY}, located at {ADDRESS OF EXPORTING COMPANY}.

If the importer is acting on behalf of the first U.S. customer, complete this paragraph:

• The corrosion resistant steel products covered by this certification were imported by {NAME OF IMPORTING COMPANY} on behalf of {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}.

• The corrosion resistant steel products covered by this certification were shipped to {NAME OF PARTY TO WHOM MERCHANDISE WAS FIRST SHIPPED IN THE UNITED STATES}, located at {ADDRESS OF SHIPMENT}.

• I have personal knowledge of the facts regarding the production of the corrosion resistant steel products identified below. ''Personal knowledge'' includes facts obtained from another party, (*e.g.,* correspondence received by the importer (or exporter) from the producer regarding the country of manufacture of the imported products);

• The corrosion resistant steel products covered by this certification were produced by {NAME OF PRODUCING COMPANY}, located at {ADDRESS OF PRODUCING COMPANY}; *for each additional company, repeat:* {NAME OF PRODUCING COMPANY}, located at {ADDRESS OF PRODUCING COMPANY}.

• The corrosion resistant steel products covered by this certification were not manufactured using hot-rolled steel and/or cold-rolled steel substrate from China.

• This certification applies to the following entries:

Producer	Entry summary No.	Entry summary line item No.	Invoice No.	Invoice line item No.

• I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, mill certificates, production records, invoices, etc.) for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of

any litigation in the United States courts regarding such entries;

• I understand that {NAME OF IMPORTING COMPANY} is required to provide this certification and supporting records, upon request, to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce);

• I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of the exporter's certification (attesting to the production and/or export of the imported merchandise identified above), and any supporting records provided by the exporter to the importer, for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries;

• I understand that {NAME OF IMPORTING COMPANY}is required to maintain and, upon request, provide a copy of the exporter's certification and any supporting records provided by the exporter to the importer, to CBP and/or Commerce;

• I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce;

• I understand that failure to maintain the required certifications, and/or failure to substantiate the claims made herein, and/or failure to allow CBP and/or Commerce to verify the claims made herein, may result in a de facto determination that all entries to which this certification applies are within the scope of the antidumping/countervailing duty order on corrosion resistant steel products from China. I understand that such finding will result in:

○ Suspension of liquidation of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met; and;

○ the requirement that the importer post applicable antidumping duty and/or countervailing duty cash deposits (as appropriate) equal to the rates determined by Commerce;

the revocation of {NAME OF IMPORTING COMPANY}'s privilege to certify future imports of corrosion resistant steel products from Malaysia as not manufactured using hot-rolled steel and/or cold-rolled steel substrate from China.

• I understand that agents of the importer, such as brokers, are not permitted to make this certification;

• This certification was completed at or prior to the time of Entry; and

• I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make materially false statements to the U.S. government.

Signature

NAME OF COMPANY OFFICIAL

TITLE

DATE

[FR Doc. 2020–03141 Filed 2–14–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Quarterly Update to Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty

AGENCY: Enforcement and Compliance, International Trade Administration Department of Commerce.

DATES: Applicable February 18, 2020.

FOR FURTHER INFORMATION CONTACT: Stephanie Moore, 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) 482–3692.

SUPPLEMENTARY INFORMATION: On November 5, 2019, the Department of Commerce (Commerce), pursuant to section 702(h) of the Trade Agreements Act of 1979 (as amended) (the Act), published the quarterly update to the annual listing of foreign government subsidies on articles of cheese subject to an in-quota rate of duty covering the period April 1, 2019 through June 30, 2019.[1] In the *Second Quarter 2019 Update,* we requested that any party that has information on foreign government subsidy programs that benefit articles of cheese subject to an in-quote rate of duty submit such information to Commerce.[2] We received no comments, information, or requests for consultation from any party.

Pursuant to section 702(h) of the Act, we hereby provide Commerce's update of subsidies on articles of cheese that were imported during the period July 1, 2019 through September 30, 2019. The appendix to this notice lists the country, the subsidy program or programs, and the gross and net amounts of each subsidy for which information is currently available.

Commerce will incorporate additional programs which are found to constitute subsidies, and additional information on the subsidy programs listed, as the information is developed. Commerce encourages any person having information on foreign government subsidy programs which benefit articles of cheese subject to an in-quota rate of duty to submit such information in writing to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, 1401 Constitution Ave. NW, Washington, DC 20230.

This determination and notice are in accordance with section 702(a) of the Act.

Dated: February 7, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

SUBSIDY PROGRAMS ON CHEESE SUBJECT TO AN IN-QUOTA RATE OF DUTY

Country	Program(s)	Gross[3] subsidy ($/lb)	Net[4] subsidy ($/lb)
28 European Union Member States[5]	European Union Restitution Payments	0.00	0.00
Canada	Export Assistance on Certain Types of Cheese	0.46	0.46
Norway	Indirect (Milk) Subsidy	0.00	0.00
	Consumer Subsidy	0.00	0.00
Total		0.00	0.00
Switzerland	Deficiency Payments	0.00	0.00

[1] *See Quarterly Update to Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty,* 84 FR 59615 (November 5, 2019) (*Second Quarter 2019 Update*).

[2] *Id.*

[3] Defined in 19 U.S.C. 1677(5).

[4] Defined in 19 U.S.C. 1677(6).

[5] The 28 member states of the European Union during the July 1 through September 30, 2019 quarter were: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.

[FR Doc. 2020–03052 Filed 2–14–20; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–888]

Carbon and Alloy Steel Threaded Rod From India: Final Affirmative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of carbon and alloy steel threaded rod (steel threaded rod) from India during the period of investigation (POI) January 1, 2018 through December 31, 2018. The final estimated subsidy rates are shown in the ''Final Determination'' section of this notice.

DATES: Applicable February 18, 2020.

FOR FURTHER INFORMATION CONTACT: Genevieve Coen or Hannah Falvey, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3251 or (202) 482–4889, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 29, 2019, Commerce published the *Preliminary Determination* of this investigation, in which we found that countervailable subsidies are being provided to producers and exporters of steel threaded rod from India.[1] On October 16, 2019, we issued a Post-Preliminary Analysis Memorandum.[2] We invited interested parties to comment on the *Preliminary Determination* and the Post-Preliminary Analysis Memorandum. We received no comments from interested parties.

Period of Investigation

The POI is January 1, 2018 through December 31, 2018.

Scope of the Investigation

The product covered by this investigation is steel threaded rod from India. For a complete description of the scope of this investigation, *see* the appendix to this notice.

Scope Comments

On July 22, 2019, we issued a Preliminary Scope Memorandum.[3] The scope case briefs were due on August 28, 2019.[4] We received no scope case briefs from interested parties. Therefore, Commerce has made no changes to the scope of this investigation since the *Preliminary Determination.*

Verification

Commerce conducted verification of the questionnaire responses provided by Mangal Steel Enterprises Limited (Mangal) between October 21 and October 24, 2019.[5] Because the second mandatory respondent in this investigation, Daksh Fasteners (Daksh), did not provide the information requested, Commerce did not conduct verification of Daksh.[6]

Analysis of Comments Received

As noted above, we received no comments in response to the *Preliminary Determination* or Post-Preliminary Analysis Memorandum. However, Commerce is revising its decision regarding the application of adverse facts available (AFA) to the Government of India (GOI) regarding the duty drawback (DDB) program.[7] Consistent with other proceedings, which we referenced in the *Preliminary Determination,*[8] for this final determination, we find that the GOI's responses regarding the DDB program did not warrant the application of AFA, but instead, the GOI's responses were insufficient to establish that the GOI has a system in place for this program that is reasonable or effective for the purposes intended.[9] Therefore, we find that this program is countervailable.[10] Because we continue to find this program countervailable, our calculations regarding this program remain unchanged for this final determination.

Methodology

We continue to find, as stated in the *Preliminary Determination,* that mandatory respondent Daksh withheld requested information, failed to provide information by the specified deadlines, and significantly impeded the proceeding, pursuant to section 776(a) of the Tariff Act of 1930, as amended (the Act). Further, we continue to find that Daksh failed to cooperate to the best of its ability to comply with our requests for information, and, accordingly, we continue to apply an adverse inference when selecting from among the facts otherwise available to determine the relevant countervailable subsidy rate, in accordance with section 776(b) of the Act. We continue to find, using AFA, that Daksh used all the programs on which Commerce initiated, and continue to apply AFA rates for each program as discussed in the *Preliminary Determination* and the Post-Preliminary Analysis Memorandum.[11]

All-Others Rate

We continue to assign the countervailable subsidy rate calculated for Mangal as the all-others rate applicable to all exporters and/or producers not individually examined.[12]

Final Determination

Commerce determines that the following estimated countervailable subsidy rates exist:

Exporter/producer	Net subsidy rate (percent)
Daksh Fasteners	211.72
Mangal Steel Enterprises Limited	6.07
All Others	6.07

[1] *See Carbon and Alloy Steel Threaded Rod from India: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination with Final Antidumping Duty Determination,* 84 FR 36570 (July 29, 2019) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Post-Preliminary Analysis Memorandum in the Countervailing Duty Investigation of Carbon and Alloy Steel Threaded Rod from India,'' dated October 16, 2019 (Post-Preliminary Analysis Memorandum).

[3] *See* Memorandum, ''Carbon and Alloy Steel Threaded Rod from India, Taiwan, Thailand, and the People's Republic of China: Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated July 22, 2019 (Preliminary Scope Memorandum).

[4] The scope case briefs were due 30 days after the publication of the *Preliminary Determination. See* Preliminary Scope Memorandum at 3. The deadline for scope rebuttal briefs was Monday, September 2, 2019.

[5] *See* Memorandum, ''Verification of the Questionnaire Responses of Mangal Steel Enterprises Limited,'' dated November 8, 2019.

[6] *See Preliminary Determination* PDM at 6–7.

[7] *Id.* at 7–8.

[8] *Id.* at 20 (citing *Certain Frozen Warmwater Shrimp from India: Final Affirmative Countervailing Duty Determination,* 78 FR 50385 (August 19, 2013) (*Shrimp from India Final Determination*), and accompanying Issues and Decision Memorandum (IDM) at ''Duty Drawback'').

[9] *See Shrimp from India Final Determination* IDM at 12 (''If such a system does not exist, or if it is not applied effectively, and the government in question does not carry out an examination of actual inputs involved to confirm which inputs are consumed in the production of the exported product, the entire amount of any exemption, deferral, remission or drawback is countervailable.'').

[10] *Id.*

[11] *Id.* at 11–15; *see also* Post-Preliminary Analysis Memorandum at 2–3.

[12] *See Preliminary Determination,* 84 FR at 36571.

Continuation of Suspension of Liquidation

As a result of our *Preliminary Determination* and pursuant to section 703(d)(1)(B) and (d)(2) of the Act, we instructed U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of the *Preliminary Determination* in the **Federal Register**. In accordance with section 703(d) of the Act, we issued instructions to CBP to discontinue the suspension of liquidation for countervailing duty purposes for subject merchandise entered, or withdrawn from warehouse, on or after November 26, 2019, but to continue the suspension of liquidation of all entries from July 29 through November 25, 2019.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a countervailing duty order, reinstate the suspension of liquidation under section 706(a) of the Act, and require a cash deposit of estimated countervailing duties for such entries of subject merchandise in the amounts indicated above. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with a final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because there are no changes from the *Preliminary Determination,* there are no new calculations to disclose.

ITC Notification

In accordance with section 705(d) of the Act, we will notify the ITC of the final affirmative determination of countervailable subsidies. In addition, we are making available to the ITC all non-privileged and non-proprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

Because the final determination in this proceeding is affirmative, in accordance with section 705(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of steel threaded rod from India no later than 45 days after this final determination. If the ITC determines that material injury, or threat of material injury, does not exist, the proceeding will be terminated, and all cash deposits will be refunded. If the ITC determines that such injury does exist, Commerce will issue a countervailing duty order directing CBP to assess, upon further instruction by Commerce, countervailing duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Notification Regarding APO

This notice serves as a reminder to parties subject to APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination is issued and published in accordance with sections 705(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: February 7, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Investigation

The merchandise covered by the scope of this investigation is carbon and alloy steel threaded rod. Steel threaded rod is certain threaded rod, bar, or studs, of carbon or alloy steel, having a solid, circular cross section of any diameter, in any straight length. Steel threaded rod is normally drawn, cold-rolled, threaded, and straightened, or it may be hot-rolled. In addition, the steel threaded rod, bar, or studs subject to this investigation are non-headed and threaded along greater than 25 percent of their total actual length. A variety of finishes or coatings, such as plain oil finish as a temporary rust protectant, zinc coating (*i.e.,* galvanized, whether by electroplating or hot-dipping), paint, and other similar finishes and coatings, may be applied to the merchandise.

Steel threaded rod is normally produced to American Society for Testing and Materials (ASTM) specifications ASTM A36, ASTM A193 B7/B7m, ASTM A193 B16, ASTM A307, ASTM A320 L7/L7M, ASTM A320 L43, ASTM A354 BC and BD, ASTM A449, ASTM F1554–36, ASTM F1554–55, ASTM F1554 Grade 105, American Society of Mechanical Engineers (ASME) specification ASME B18.31.3, and American Petroleum Institute (API) specification API 20E. All steel threaded rod meeting the physical description set forth above is covered by the scope of this investigation, whether or not produced according to a particular standard. Subject merchandise includes material matching the above description that has been finished, assembled, or packaged in a third country, including by cutting, chamfering, coating, or painting the threaded rod, by attaching the threaded rod to, or packaging it with, another product, or any other finishing, assembly, or packaging operation that would not otherwise remove the merchandise from the scope of this investigation if performed in the country of manufacture of the threaded rod.

Carbon and alloy steel threaded rod are also included in the scope of this investigation whether or not imported attached to, or in conjunction with, other parts and accessories such as nuts and washers. If carbon and alloy steel threaded rod are imported attached to, or in conjunction with, such non-subject merchandise, only the threaded rod is included in the scope.

Excluded from the scope of this investigation are: (1) Threaded rod, bar, or studs which are threaded only on one or both ends and the threading covers 25 percent or less of the total actual length; and (2) stainless steel threaded rod, defined as steel threaded rod containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with our without other elements.

Excluded from the scope of the antidumping investigation on steel threaded rod from the People's Republic of China is any merchandise covered by the existing antidumping order on Certain Steel Threaded Rod from the People's Republic of China. *See Certain Steel Threaded Rod from the People's Republic of China: Notice of Antidumping Duty Order,* 74 FR 17154 (April 14, 2009).

Specifically excluded from the scope of this investigation is threaded rod that is imported as part of a package of hardware in conjunction with a ready-to-assemble piece of furniture. Steel threaded rod is currently classifiable under subheadings 7318.15.5051, 7318.15.5056, and 7318.15.5090 of the Harmonized Tariff Schedule of the United States (HTSUS). Subject merchandise may also enter under subheading 7318.15.2095 and 7318.19.0000 of the HTSUS. The HTSUS subheadings are provided for convenience and U.S. Customs purposes only. The written description of the scope is dispositive.

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–026; C–570–027]

Certain Corrosion-Resistant Steel Products From the People's Republic of China: Affirmative Preliminary Determination of Circumvention Involving Costa Rica

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that imports of certain corrosion-resistant steel products (CORE) completed in Costa Rica, using hot-rolled steel (HRS) and/or cold-rolled steel (CRS) flat products manufactured in the People's Republic of China (China), are circumventing the antidumping duty (AD) and countervailing duty (CVD) orders on CORE from China.

DATES: Applicable February 18, 2020.

FOR FURTHER INFORMATION CONTACT: Ariela Garvett, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3609.

SUPPLEMENTARY INFORMATION:

Background

On August 12, 2019, Commerce self-initiated country-wide anti-circumvention inquiries of the *China CORE Orders* [1] covering Chinese-origin HRS and/or CRS exported to various countries, including Costa Rica, for completion into CORE and subsequently exported to the United States.[2] In the *Initiation Notice,* Commerce initiated the instant anti-circumvention inquiries based on available information and an analysis pursuant to section 781(b) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.225(h), to determine whether the importation of the Chinese-origin HRS or CRS substrate for completion into CORE in Costa Rica and subsequent exportation of that CORE to the United States constitutes circumvention of the *China CORE Orders.*

For a complete description of the record developed since the initiation of these inquiries, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Orders

The products covered by these orders are certain flat-rolled steel products, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel- or iron-based alloys, whether or not corrugated or painted, varnished, laminated, or coated with plastics or other non-metallic substances in addition to the metallic coating. For a complete description of the scope of the orders, *see* the Preliminary Decision Memorandum.

Scope of the Anti-Circumvention Inquiries

These anti-circumvention inquiries cover CORE completed in Costa Rica from HRS or CRS substrate input manufactured in China and subsequently exported from Costa Rica to the United States (merchandise subject to these inquiries).

Methodology

Commerce is conducting these anti-circumvention inquiries in accordance with section 781(b) of the Act and 19 CFR 351.225(h). Because an interested party (*i.e.,* Metas A.) did not cooperate to the best of its abilities in responding to Commerce's requests for information, we have based parts of our preliminary determination on the facts available, with adverse inferences, pursuant to sections 776(a) and (b) of the Act. For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

Preliminary Finding

As detailed in the Preliminary Decision Memorandum, we preliminarily determine that CORE completed in Costa Rica from HRS and/or CRS substrate sourced from China is circumventing the *China CORE Orders.* We therefore preliminarily determine that it is appropriate to include this merchandise within the *China CORE Orders* and to instruct U.S. Customs and Border Protection (CBP) to suspend liquidation of any entries of CORE from Costa Rica produced from HRS and/or CRS from China.

Suspension of Liquidation

As stated above, Commerce has made a preliminary affirmative determination that imports of CORE completed in Costa Rica, using HRS and/or CRS flat products manufactured in China, are circumventing the *China CORE Orders.* In accordance with 19 CFR 351.225(l)(2), Commerce will direct CBP to suspend liquidation and to require a cash deposit of estimated duties on unliquidated entries of CORE produced in Costa Rica, as appropriate, that were entered, or withdrawn from warehouse, for consumption on or after August 12, 2019, the date of initiation of the anti-circumvention inquiries. The suspension of liquidation instructions will remain in effect until further notice.

CORE produced in Costa Rica from HRS and/or CRS that is not of Chinese origin is not subject to these inquiries. However, imports of such merchandise are subject to certification requirements, and cash deposits may be required if the certification requirements are not satisfied. Accordingly, if an importer imports CORE from Costa Rica and claims that the CORE was not produced from HRS and/or CRS substrate manufactured in China, the importer and exporter are required to meet the certification and documentation requirements described in Appendices II, III, and IV, in order for cash deposits

[1] *See Certain Corrosion-Resistant Steel Flat Products from India, Italy, the People's Republic of China, the Republic of Korea, and Taiwan: Amended Final Affirmative Antidumping Duty Determination for India and Taiwan, and Antidumping Duty Orders,* 81 FR 48390 (July 25, 2016); *see also Certain Corrosion-Resistant Steel Products from India, Italy, Republic of Korea, and the People's Republic of China: Countervailing Duty Order,* 81 FR 48387 (July 25, 2016) (collectively, *China CORE Orders*).

[2] The notice of initiation subsequently published in the **Federal Register** on August 21, 2019. *See Corrosion-Resistant Steel Products from the People's Republic of China: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders,* 84 FR 43585 (August 21, 2019) (*Initiation Notice*) and accompanying Memorandum, ''Certain Corrosion-Resistant Steel Products from the People's Republic of China: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders,'' dated August 12, 2019.

[3] *See* Memorandum, ''Preliminary Decision Memorandum for the Anti-Circumvention Inquiries Involving Costa Rica of the Antidumping and Countervailing Duty Orders on Certain Corrosion-Resistant Steel Products from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

pursuant to the *China CORE Orders* not to be required.

In the situation where no certification is provided for an entry, and AD/CVD orders from China therefore potentially apply to that entry, Commerce intends to instruct CBP to suspend liquidation of the entry and collect cash deposits at the rates applicable to the *China CORE Orders* (*i.e.,* the AD rate established for the China-wide entity (199.43 percent) and the CVD rate established for the China all-others rate (39.05 percent)).[4]

Commerce preliminarily determines that the following company is not eligible for the certification process: Metas A. Additionally, exporters are not eligible to certify shipments of merchandise produced by Metas A. Further, importers of CORE from Costa Rica that is produced and/or exported by this ineligible company are similarly ineligible for the certification process with regard to those imports.

Verification

As provided in 19 CFR 351.307, Commerce intends to verify information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the final verification report is issued in these anti-circumvention inquiries, unless the Secretary alters the time limit. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[5] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in these anti-circumvention inquiries are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington DC 20230 at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

International Trade Commission Notification

Commerce, consistent with section 781(e) of the Act, has notified the U.S. International Trade Commission (ITC) of this preliminary determination to include the merchandise subject to these anti-circumvention inquiries within the *China CORE Orders.* Pursuant to section 781(e) of the Act, the ITC may request consultations concerning Commerce's proposed inclusion of the merchandise subject to these inquiries. If, after consultations, the ITC believes that a significant injury issue is presented by the proposed inclusion, it will have 60 days from the date of notification by Commerce to provide written advice.

Notification to Interested Parties

This determination is issued and published in accordance with section 781(b) of the Act and 19 CFR 351.225(f).

Dated: February 7, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Orders
IV. Scope of the Anti-Circumvention Inquiries
V. Period of Inquiries
VI. Surrogate Countries and Methodology for Valuing Inputs from China
VII. Statutory Framework
VIII. Use of Facts of Available with an Adverse Inference
IX. Anti-Circumvention Determination
X. Country-Wide Determination
XI. Certification for Not Using Chinese-Origin HRS and/or CRS
XII. Verification
XIII. Recommendation

Appendix II

Certification Requirements

If an importer imports certain corrosion-resistant steel products (CORE) from Costa Rica and claims that the CORE was not produced from hot-rolled steel and/or cold-rolled steel substrate (substrate) manufactured in the People's Republic of China (China), the importer is required to complete and maintain the importer certification attached hereto as Appendix IV and all supporting documentation. Where the importer uses a broker to facilitate the entry process, it should obtain the entry number from the broker. Agents of the importer, such as brokers, however, are not permitted to make this certification on behalf of the importer.

The exporter is required to complete and maintain the exporter certification, attached as Appendix III, and is further required to provide the importer a copy of that certification and all supporting documentation.

For shipments and/or entries on or after August 12, 2019 through March 7, 2020, for which certifications are required, importers and exporters should complete the required certification within 30 days of the publication of this notice in the **Federal Register**. Accordingly, where appropriate, the relevant bullet in the certification should be edited to reflect that the certification was completed within the time frame specified above. For example, the bullet in the importer certification that reads: ''This certification was completed at or prior to the time of Entry,'' could be edited as follows: ''The imports referenced herein entered before March 8, 2020. This certification was completed on mm/dd/yyyy, within 30 days of the **Federal Register** notice publication of the preliminary determination of circumvention.'' Similarly, the bullet in the exporter certification that reads, ''This certification was completed at or prior to the time of shipment,'' could be edited as follows: ''The shipments/products referenced herein shipped before March 8, 2020. This certification was completed on mm/dd/yyyy, within 30 days of the **Federal Register** notice publication of the preliminary determination of circumvention. For such entries/shipments, importers and exporters each have the option to complete a blanket certification covering multiple entries/shipments, individual certifications for each entry/shipment, or a combination thereof.

For shipments and/or entries on or after March 8, 2020, for which certifications are required, importers should complete the required certification at or prior to the date of Entry and exporters should complete the required certification and provide it to the importer at or prior to the date of shipment.

The importer and Costa Rican exporter are also required to maintain sufficient documentation supporting their certifications. The importer will not be required to submit the certifications or supporting documentation to U.S. Customs and Border Protection (CBP) as part of the entry process at this time. However, the importer and the exporter will be required to present the certifications and supporting documentation, to Commerce and/or CBP, as applicable, upon request by the respective agency. Additionally, the claims made in the certifications and any supporting documentation are subject to verification by Commerce and/or CBP. The importer and exporter are required to maintain the certifications (the importer must retain both certifications) and supporting documentation for the later of: (1) A period of five years from the date of entry or (2) a period of three years

[4] *See China CORE Orders,* 81 FR at 48389 and 48393.

[5] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

after the conclusion of any litigation in United States courts regarding such entries.

In the situation where no certification is provided for an entry, Commerce intends to instruct CBP to suspend liquidation of the entry and collect cash deposits at the rate applicable to the *CORE China Orders* (*i.e.,* the AD rate established for the China-wide entity (199.43 percent) and the CVD rate established for China all-others rate (39.05 percent)).

Appendix III

Exporter Certification

I hereby certify that:

• My name is {COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF EXPORTING COMPANY}, located at {ADDRESS OF EXPORTING COMPANY};

• I have direct personal knowledge of the facts regarding the production and exportation of the corrosion resistant steel products identified below. ''Direct personal knowledge'' refers to facts the certifying party is expected to have in its own books and records. For example, an exporter should have direct personal knowledge of the producer's identity and location.

• The corrosion resistant steel products covered by this certification were produced by {NAME OF PRODUCING COMPANY}, located at {ADDRESS OF PRODUCING COMPANY}; *for each additional company, repeat:* {NAME OF PRODUCING COMPANY}, located at {ADDRESS OF PRODUCING COMPANY}

• The corrosion resistant steel products produced in Costa Rica were not manufactured using hot-rolled steel and/or cold-rolled steel substrate from China;

• This certification applies to the following sales:

Producer	Invoice No.	Invoice line item No.

• The corrosion resistant steel products covered by this certification were sold to {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}.

• The corrosion resistant steel products covered by this certification were shipped to {NAME OF PARTY TO WHOM MERCHANDISE WAS SHIPPED}, located at {ADDRESS OF SHIPMENT}.

• I understand that {NAME OF EXPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, mill certificates, production records, invoices, etc.) for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in the United States courts regarding such entries;

• I understand that {NAME OF EXPORTING COMPANY} must provide a copy of this Exporter Certification to the U.S. importer by the time of shipment;

• I understand that {NAME OF EXPORTING COMPANY} is required to provide a copy of this certification and supporting records, upon request, to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce);

• I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce;

• I understand that failure to maintain the required certification, and/or failure to substantiate the claims made herein, and/or failure to allow CBP and/or Commerce to verify the claims made herein, may result in a de facto determination that all sales to which this certification applies are within the scope of the antidumping/countervailing duty order on corrosion resistant steel products from China. I understand that such finding will result in:

○ Suspension of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met; and

○ the requirement that the importer post applicable antidumping duty and/or countervailing duty cash deposits (as appropriate) equal to the rates as determined by Commerce;

○ the revocation of {NAME OF EXPORTING COMPANY}'s privilege to certify future exports of corrosion resistant steel products from Costa Rica as not manufactured using hot-rolled steel and/or cold-rolled steel substrate from China.

• This certification was completed at or prior to the time of shipment; and

• I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government.

Signature

NAME OF COMPANY OFFICIAL
TITLE
DATE

Appendix IV

Importer Certification

I hereby certify that:

• My name is {IMPORTING COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF IMPORTING COMPANY}, located at {ADDRESS OF IMPORTING COMPANY}.

• I have direct personal knowledge of the facts regarding the importation into the Customs territory of the United States of the corrosion resistant steel products produced in Costa Rica that entered under entry number(s), identified below, and which are covered by this certification. ''Direct personal knowledge'' refers to facts the certifying party is expected to have in its own records. For example, the importer should have direct personal knowledge of the importation of the product (*e.g.,* the name of the exporter) in its records;

• The corrosion resistant steel products covered by this certification were exported by {NAME OF EXPORTING COMPANY}, located at {ADDRESS OF EXPORTING COMPANY}.

If the importer is acting on behalf of the first U.S. customer, complete this paragraph:

• The corrosion resistant steel products covered by this certification were imported by {NAME OF IMPORTING COMPANY} on behalf of {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}.

• The corrosion resistant steel products covered by this certification were shipped to {NAME OF PARTY TO WHOM MERCHANDISE WAS FIRST SHIPPED IN THE UNITED STATES}, located at {ADDRESS OF SHIPMENT}.

• I have personal knowledge of the facts regarding the production of the corrosion resistant steel products identified below. ''Personal knowledge'' includes facts obtained from another party, (*e.g.,* correspondence received by the importer (or exporter) from the producer regarding the country of manufacture of the imported products);

• The corrosion resistant steel products covered by this certification were produced by {NAME OF PRODUCING COMPANY}, located at {ADDRESS OF PRODUCING COMPANY}; *for each additional company, repeat:* {NAME OF PRODUCING COMPANY}, located at {ADDRESS OF PRODUCING COMPANY}.

• The corrosion resistant steel products covered by this certification were not manufactured using hot-rolled steel and/or cold-rolled steel substrate from China.

• This certification applies to the following entries:

Producer	Entry summary No.	Entry summary line item No.	Invoice No.	Invoice line item No.

• I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, mill certificates, production records, invoices, etc.) for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in the United States courts regarding such entries;

• I understand that {NAME OF IMPORTING COMPANY} is required to provide this certification and supporting records, upon request, to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce);

• I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of the exporter's certification (attesting to the production and/or export of the imported merchandise identified above), and any supporting records provided by the exporter to the importer, for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries;

• I understand that {NAME OF IMPORTING COMPANY} is required to maintain and, upon request, provide a copy of the exporter's certification and any supporting records provided by the exporter to the importer, to CBP and/or Commerce;

• I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce;

• I understand that failure to maintain the required certifications, and/or failure to substantiate the claims made herein, and/or failure to allow CBP and/or Commerce to verify the claims made herein, may result in a de facto determination that all entries to which this certification applies are within the scope of the antidumping/countervailing duty order on corrosion resistant steel products from China. I understand that such finding will result in:

○ Suspension of liquidation of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met; and;

○ the requirement that the importer post applicable antidumping duty and/or countervailing duty cash deposits (as appropriate) equal to the rates determined by Commerce;

the revocation of {NAME OF IMPORTING COMPANY}'s privilege to certify future imports of corrosion resistant steel products from Costa Rica as not manufactured using hot-rolled steel and/or cold-rolled steel substrate from China.

• I understand that agents of the importer, such as brokers, are not permitted to make this certification;

• This certification was completed at or prior to the time of Entry; and

• I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government.

Signature
NAME OF COMPANY OFFICIAL
TITLE
DATE

[FR Doc. 2020–03139 Filed 2–14–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–105]

Carbon and Alloy Steel Threaded Rod From the People's Republic of China: Final Affirmative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of carbon and alloy steel threaded rod (steel threaded rod) from the People's Republic of China (China).

DATES: Applicable February 18, 2020.

FOR FURTHER INFORMATION CONTACT: Thomas Schauer or Allison Hollander, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0410 or (202) 482–2805, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 29, 2019, Commerce published the *Preliminary Determination* in the **Federal Register**.[1] In addition to the Government of China (GOC), the selected mandatory respondents in this investigation are Ningbo Zhongjiang High Strength Bolts Co., Ltd. (Zhongjiang Bolts) and Zhejiang Junyue Standard Part Co., Ltd. (Junyue). In the *Preliminary Determination,* and in accordance with section 705(a)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.210(b)(4), Commerce aligned the final countervailable duty (CVD) determination with the final antidumping duty (AD) determination. The revised deadline for the final determination of this investigation is now February 7, 2020. On October 2, 2019, Commerce issued its Post-Preliminary Analysis.[2]

A summary of the events that occurred since Commerce published the *Preliminary Determination,* as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.[3] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Period of Investigation

The period of investigation is January 1, 2018 through December 31, 2018.

Scope of the Investigation

The products covered by this investigation are steel threaded rod from China. For a full description of the scope of the investigation, *see* Appendix I.

Scope Comments

On July 22, 2019, we issued a Preliminary Scope Memorandum.[4] The scope case briefs were due on August 28, 2019.[5] We received no scope case briefs from interested parties. Therefore, Commerce has made no changes to the scope of this investigation since the *Preliminary Determination.*

Verification

As provided in section 782(i) of the Act, in November 2019, Commerce

[1] *See Carbon and Alloy Steel Threaded Rod from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination with Final Antidumping Duty Determination,* 84 FR 36578 (July 29, 2019) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Decision Memorandum for the Post-Preliminary Analysis in the Countervailing Duty Investigation of Carbon and Alloy Steel Threaded Rod from the People's Republic of China,'' dated October 2, 2019 (Post-Preliminary Analysis).

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Determination in the Countervailing Duty Investigation of Carbon and Alloy Steel Threaded Rod from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See* Memorandum, ''Carbon and Alloy Steel Threaded Rod from India, Taiwan, Thailand, and the People's Republic of China: Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated July 22, 2019 (Preliminary Scope Memorandum).

[5] The scope case briefs were due 30 days after the publication of the *Preliminary Determination. See* Preliminary Scope Memorandum at 3.

verified the subsidy information reported by Zhongjiang Bolts and Junyue. We used standard verification procedures, including an examination of relevant accounting and production records, and original source documents provided by Junyue and Zhongjiang Bolts.

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation and the issues raised in the case and rebuttal briefs by parties in this investigation are discussed in the Issues and Decision Memorandum. For a list of the issues raised by parties, and to which we responded in the Issues and Decision Memorandum, *see* Appendix II of this notice.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Act. For each of the subsidy programs found countervailable, Commerce determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[6]

Use of Adverse Facts Available

In making this final determination, Commerce relied, in part, on facts available and, because the GOC and Junyue did not act to the best of their ability in responding to Commerce's requests for information, we drew an adverse inference where appropriate in selecting from among the facts otherwise available, pursuant to sections 776(a) and (b) of the Act. For further information, *see* the section ''Use of Facts Otherwise Available and Adverse Inferences'' and Comments 1 through 3, 6, and 7 in the Issues and Decision Memorandum.

Changes Since the Preliminary Determination

Based on our analysis of our findings at verification and the comments received, we have made certain changes to the countervailable subsidy rate calculations. For discussion of these changes, *see* the Issues and Decision Memorandum.

All-Others Rate

In accordance with section 705(c)(5)(A)(i) of the Act, for companies not individually examined, we apply an all-others rate, which is normally calculated by weighting the subsidy rates of the mandatory respondents by those companies' exports of the subject merchandise to the United States. Under section 705(c)(5)(A)(i) of the Act, the all-others rate should exclude zero and *de minimis* rates or any rates based entirely on facts otherwise available pursuant to section 776 of the Act.

Commerce calculated individual estimated countervailable subsidy rates for Junyue and Zhongjiang Bolts that are not zero, *de minimis,* or based entirely on facts otherwise available. Commerce calculated the all-others rate using a weighted-average of the estimated subsidy rates calculated for the examined respondents using each company's publicly ranged U.S. sales quantities for the merchandise under consideration.[7]

Final Determination

Company	Net subsidy rate (percent)
Ningbo Zhongjiang High Strength Bolts Co., Ltd	31.02
Zhejiang Junyue Standard Part Co., Ltd	66.81
All Others	41.17

We determine the countervailable subsidy rates to be:

Disclosure

We intend to disclose the calculations performed to parties in this proceeding within five days after public announcement of the final determination in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

As a result of our *Preliminary Determination* and pursuant to section 703(d)(1)(B) and (d)(2) of the Act, we instructed U.S. Customs and Border Protection (CBP) to suspend liquidation of all steel threaded rod from China, that were entered, or withdrawn from warehouse, for consumption on or after July 29, 2019, the date of the publication of the *Preliminary Determination* in the **Federal Register**. In accordance with section 703(d) of the Act, we instructed CBP to discontinue the suspension of liquidation for CVD purposes for subject merchandise entered, or withdrawn from warehouse, on or after November 26, 2019, but continue the suspension of liquidation of all entries from July 29 through November 25, 2019.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a CVD order and will reinstate the suspension of liquidation under section 706(a) of the Act and will require a cash deposit of estimated countervailable duties for such entries of subject merchandise in the amounts indicated above. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all cash deposits will be refunded or canceled.

ITC Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our determination. Because the final determination in this proceeding is affirmative, in accordance with section 705(b) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of steel threaded rod from China no later than 45 days after our final determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

Notification Regarding APO

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to the parties subject to APO of their

[6] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[7] With two respondents under examination, Commerce normally calculates (A) a weighted-average of the estimated subsidy rates calculated for the examined respondents; (B) a simple average of the estimated subsidy rates calculated for the examined respondents; and (C) a weighted-average of the estimated subsidy rates calculated for the examined respondents using each company's publicly-ranged U.S. sale quantities for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010). As complete publicly ranged sales data was available, Commerce based the all-others rate on the publicly ranged sales data of the mandatory respondents. In addition, using the same methodology, Commerce calculated an all-others export subsidy rate of 16.52 percent, an all-others subsidy rate for the provision of steel bar at less than adequate remuneration (LTAR) of 12.75 percent, and an all-others subsidy rate for the provision of wire rod at LTAR of 9.75 percent. For a complete analysis of the data, *see* the All-Others' Rate Calculation Memorandum, dated concurrently with this notice.

responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination is issued and published in accordance with sections 705(d) and 77(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: February 7, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by the scope of this investigation is carbon and alloy steel threaded rod. Steel threaded rod is certain threaded rod, bar, or studs, of carbon or alloy steel, having a solid, circular cross section of any diameter, in any straight length. Steel threaded rod is normally drawn, cold-rolled, threaded, and straightened, or it may be hot-rolled. In addition, the steel threaded rod, bar, or studs subject to this investigation are non-headed and threaded along greater than 25 percent of their total actual length. A variety of finishes or coatings, such as plain oil finish as a temporary rust protectant, zinc coating (*i.e.,* galvanized, whether by electroplating or hot-dipping), paint, and other similar finishes and coatings, may be applied to the merchandise.

Steel threaded rod is normally produced to American Society for Testing and Materials (ASTM) specifications ASTM A36, ASTM A193 B7/B7m, ASTM A193 B16, ASTM A307, ASTM A320 L7/L7M, ASTM A320 L43, ASTM A354 BC and BD, ASTM A449, ASTM F1554–36, ASTM F1554–55, ASTM F1554 Grade 105, American Society of Mechanical Engineers (ASME) specification ASME B18.31.3, and American Petroleum Institute (API) specification API 20E. All steel threaded rod meeting the physical description set forth above is covered by the scope of this investigation, whether or not produced according to a particular standard.

Subject merchandise includes material matching the above description that has been finished, assembled, or packaged in a third country, including by cutting, chamfering, coating, or painting the threaded rod, by attaching the threaded rod to, or packaging it with, another product, or any other finishing, assembly, or packaging operation that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the threaded rod.

Carbon and alloy steel threaded rod are also included in the scope of this investigation whether or not imported attached to, or in conjunction with, other parts and accessories such as nuts and washers. If carbon and alloy steel threaded rod are imported attached to, or in conjunction with, such non-subject merchandise, only the threaded rod is included in the scope.

Excluded from the scope of this investigation are: (1) Threaded rod, bar, or studs which are threaded only on one or both ends and the threading covers 25 percent or less of the total actual length; and (2) stainless steel threaded rod, defined as steel threaded rod containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with our without other elements.

Excluded from the scope of the antidumping investigation on steel threaded rod from the People's Republic of China is any merchandise covered by the existing antidumping order on Certain Steel Threaded Rod from the People's Republic of China. *See* Certain Steel Threaded Rod from the People's Republic of China: Notice of Antidumping Duty Order, 74 FR 17154 (April 14, 2009).

Specifically excluded from the scope of this investigation is threaded rod that is imported as part of a package of hardware in conjunction with a ready-to-assemble piece of furniture. Steel threaded rod is currently classifiable under subheadings 7318.15.5051, 7318.15.5056, and 7318.15.5090 of the Harmonized Tariff Schedule of the United States (HTSUS). Subject merchandise may also enter under subheading 7318.15.2095 and 7318.19.0000 of the HTSUS. The HTSUS subheadings are provided for convenience and U.S. Customs purposes only. The written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Final Decision Memorandum

I. Summary
II. Background
III. Scope of the Investigation
IV. Use of Facts Otherwise Available and Adverse Inferences
V. Subsidies Valuation Information
VI. Analysis of Programs
VII. Analysis of Comments
Comment 1: Whether the Provision of Steel Bar and Wire Rod at Less Than Adequate Remuneration (LTAR) Is Specific
Comment 2: Whether the Chinese Market for Steel Bar and Wire Rod Is Distorted
Comment 3: Whether Certain Chinese Producers of Steel Bar and Wire Rod Are Authorities
Comment 4: Whether To Revise the Steel Bar and Wire Rod Benchmarks
Comment 5: Whether To Revise the Ocean Freight Benchmark
Comment 6: Whether To Countervail Export Buyer's Credit
Comment 7: Whether To Apply Adverse Facts Available (AFA) to Junyue
Comment 8: Whether To Countervail Electricity Junyue Purchased from a Private Supplier
Comment 9: Whether To Treat One of Zhongjiang Bolt's Self-Reported Subsidies as an Export Subsidy.
VIII. Recommendation

[FR Doc. 2020–03047 Filed 2–14–20; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–120]

Certain Vertical Shaft Engines Between 223cc and 999cc, and Parts Thereof From the People's Republic of China: Initiation of Countervailing Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable February 4, 2020.

FOR FURTHER INFORMATION CONTACT: Andrew Huston, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4261.

SUPPLEMENTARY INFORMATION:

The Petition

On January 15, 2020, the U.S. Department of Commerce (Commerce) received a countervailing duty (CVD) petition concerning imports of certain vertical shaft engines between 223cc and 999cc, and parts thereof (vertical shaft engines) from the People's Republic of China (China) filed in proper form on behalf of the Coalition of American Vertical Engine Producers and its individual members (the petitioner or the Coalition).[1] The Petition was accompanied by an antidumping duty (AD) petition concerning imports of vertical shaft engines from China.

On January 17, 2020, Commerce requested supplemental information pertaining to certain aspects of the Petition,[2] to which the petitioner filed its response on January 22, 2020.[3] On January 27, 2020, Commerce had a phone conversation with the petitioner requesting that it address certain

[1] *See* Petitioner's Letter, ''Petitions for the Imposition of Antidumping and Countervailing Duties on Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the People's Republic of China,'' dated January 15, 2020 (the Petition).

[2] *See* Commerce's Letter, ''Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Certain Vertical Shaft Engines Between 223cc and 999cc, and Parts Thereof from the People's Republic of China: Supplemental Questions,'' dated January 17, 2020.

[3] *See* Petitioner's Letter, ''Response to Supplemental Questions Concerning Volume I of the Petitions for the Imposition of Antidumping and Countervailing Duties Pursuant to Sections 701 and 731 of the Tariff Act of 1930, As Amended on Certain Vertical Shaft Engines Between 223cc and 999cc, and Parts Thereof from the People's Republic of China,'' dated January 22, 2020 (General Issues Supplement).

issues.[4] The petitioner filed responses to these requests on January 29, 2020.[5]

In accordance with section 702(b)(1) of the Tariff Act of 1930, as amended (the Act), the petitioner alleges that the Government of China (GOC) is providing countervailable subsidies, within the meaning of sections 701 and 771(5) of the Act, to producers of vertical shaft engines in China, and that such imports are materially injuring, or threatening material injury to, the domestic industry producing vertical shaft engines in the United States. Consistent with section 702(b)(1) of the Act and 19 CFR 351.202(b), for those alleged programs on which we are initiating a CVD investigation, the Petition is supported by information reasonably available to the petitioner supporting its allegations.

Commerce finds that the petitioner filed the Petition on behalf of the domestic industry because the petitioner is an interested party as defined in sections 771(9)(C) and (E) of the Act. Commerce also finds that the petitioner demonstrated sufficient industry support with respect to the initiation of the requested CVD investigation.[6]

Period of Investigation

Because the Petition was filed on January 15, 2020, the period of investigation (POI) is January 1, 2019 through December 31, 2019.[7]

Scope of the Investigation

The merchandise covered by this investigation is vertical shaft engines from China. For a full description of the scope of this investigation, *see* the appendix to this notice.

Comments on Scope of the Investigation

As discussed in the *Preamble* to Commerce's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage (*i.e.,* scope).[8] Commerce will consider all comments received from interested parties and, if necessary, will consult with interested parties prior to the issuance of the preliminary determination. If scope comments include factual information,[9] all such factual information should be limited to public information. To facilitate preparation of its questionnaires, Commerce requests that all interested parties submit scope comments by 5:00 p.m. Eastern Time (ET) on February 24, 2020, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. ET on March 5, 2020, which is 10 calendar days from the initial comment deadline.[10]

Commerce requests that any factual information the parties consider relevant to the scope of the investigation be submitted during this time period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigation may be relevant, the party may contact Commerce and request permission to submit the additional information. All such comments must also be filed on the record of the concurrent AD and CVD investigations.

Filing Requirements

All submissions to Commerce must be filed electronically using Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS).[11] An electronically filed document must be received successfully in its entirety by the time and date it is due. Documents exempted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

Consultations

Pursuant to sections 702(b)(4)(A)(i) and (ii) of the Act, Commerce notified the GOC of the receipt of the Petition and provided it the opportunity for consultations with respect to the CVD Petition.[12] The GOC did not request consultations.

Determination of Industry Support for the Petition

Section 702(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 702(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 702(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, Commerce shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs Commerce to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both Commerce and the ITC must apply the same statutory definition regarding the domestic like product,[13] they do so for different purposes and pursuant to a separate and distinct authority. In addition, Commerce's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[14]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like,

[4] *See* Memorandum, ''Certain Vertical Shaft Engines Between 223cc and 999cc, and Parts Thereof from the People's Republic of China: Call to Counsel,'' dated January 27, 2020.

[5] *See* Petitioner's Letter, ''Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the People's Republic of China: Responses to Second Supplemental Questions Concerning Volume I of the Petitions,'' dated January 29, 2020 (Second General Issues Supplement).

[6] *See* ''Information Relating to the Degree of Industry Support for the Petition'' section, *infra.*

[7] *See* 19 CFR 351.204(b)(2).

[8] *See Antidumping Duties; Countervailing Duties,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

[9] *See* 19 CFR 351.102(b)(21) (defining ''factual information'').

[10] *See* 19 CFR 351.303(b).

[11] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011); *see also Enforcement and Compliance; Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014) for details of Commerce's electronic filing requirements, effective August 5, 2011. Information on using ACCESS can be found at *https://access.trade.gov/help.aspx* and a handbook can be found at *https://access.trade.gov/help/Handbook%20on%20Electronic%20Filling%20Procedures.pdf.*

[12] *See* Commerce's Letter, ''Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the People's Republic of China: Invitation for Consultation to Discuss the Countervailing Duty Petition,'' dated January 15, 2020.

[13] *See* section 771(10) of the Act.

[14] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F. 2d 240 (Fed. Cir. 1989)).

most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioner does not offer a definition of the domestic like product distinct from the scope of the investigation.[15] Based on our analysis of the information submitted on the record, we have determined that vertical shaft engines, as defined in the scope, constitute a single domestic like product, and we have analyzed industry support in terms of that domestic like product.[16]

In determining whether the petitioner has standing under section 702(c)(4)(A) of the Act, we considered the industry support data contained in the Petition with reference to the domestic like product as defined in the ''Scope of the Investigation,'' in the appendix to this notice. To establish industry support, the petitioner provided 2019 shipments of the domestic like product for members of the Coalition.[17] The petitioner estimated the production of the domestic like product for the entire domestic industry based on U.S. shipment data, export data, and its own knowledge of the industry, because shipments and production of vertical shaft engines correlate with one another and shipments are a reasonable proxy for production in the vertical shaft engines industry.[18] The petitioner compared the 2019 shipments of the Coalition to the estimated total shipments of the domestic like product for the entire domestic industry.[19] We relied on data provided by the petitioner for purposes of measuring industry support.[20]

Our review of the data provided in the Petition, the General Issues Supplement, the Second General Issues Supplement, and other information readily available to Commerce indicates that the petitioner has established industry support for the Petition.[21] First, the Petition established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, Commerce is not required to take further action in order to evaluate industry support (*e.g.,* polling).[22] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petition account for at least 25 percent of the total production of the domestic like product.[23] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition.[24] Accordingly, Commerce determines that the Petition was filed on behalf of the domestic industry within the meaning of section 702(b)(1) of the Act.[25]

Injury Test

Because China is a ''Subsidies Agreement Country'' within the meaning of section 701(b) of the Act, section 701(a)(2) of the Act applies to these investigations. Accordingly, the ITC must determine whether imports of the subject merchandise from China materially injure, or threaten material injury to, a U.S. industry.

Allegations and Evidence of Material Injury and Causation

The petitioner alleges that imports of the subject merchandise are benefitting from countervailable subsidies and that such imports are causing, or threaten to cause, material injury to the U.S. industry producing the domestic like product. In addition, the petitioner alleges that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[26] In CVD petitions, section 771(24)(B) of the Act provides that imports of subject merchandise from developing and least developed countries must exceed the negligibility threshold of four percent.

The petitioner contends that the industry's injured condition is illustrated by a significant and increasing volume of subject imports; reduced market share; underselling and price depression or suppression; lost sales and revenues; and a decline in the domestic industry's financial performance and profitability.[27] We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, causation, as well as cumulation, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.[28]

Initiation of CVD Investigation

Based upon the examination of the Petition on vertical shaft engines from China, we find that the Petition meets the requirements of section 702 of the Act. Therefore, we are initiating a CVD investigation to determine whether imports of vertical shaft engines from China benefit from countervailable subsidies conferred by the GOC. Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation on each of the alleged programs. For a full discussion of the basis for our decision to initiate on each program, *see* China CVD Initiation Checklist.[29] A public

[15] *See* Volume I of the Petition, at 16–17; *see also* General Issues Supplement at 3–5.

[16] For a discussion of the domestic like product analysis as applied to these cases and information regarding industry support, *see* Antidumping Duty Investigation Initiation Checklist: Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the People's Republic of China (China AD Initiation Checklist) at Attachment II, ''Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the People's Republic of China'' (Attachment II), dated concurrently with this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Commerce building.

[17] *See* Volume I of the Petition, at 2–3 and Exhibits I–5 and I–6; *see also* General Issues Supplement at 6–9 and Exhibits Supp–I–2 and Supp–I–3; and Second General Issues Supplement, at Exhibit 2Supp–I–2.

[18] *See* Volume I of the Petition, at Exhibit I–6; *see also* General Issues Supplement, at 6–9 and Exhibits Supp–I–2 and Supp–I–3; and Second General Issues Supplement, at Exhibit 2Supp–I–2.

[19] *See* General Issues Supplement, at 6–9 and Exhibits Supp–I–2 and Supp–I–3.

[20] *See* Volume I of the Petition, at 2–3 and Exhibits I–5 and I–6; *see also* General Issues Supplement at 6–9 and Exhibits Supp–I–2 and Supp–I–3; and Second General Issues Supplement, at Exhibit 2Supp–I–2. For further discussion, *see* China AD Initiation Checklist, at Attachment II.

[21] *See* China AD Initiation Checklist, at Attachment II.

[22] *See* section 702(c)(4)(D) of the Act; *see also* China AD Initiation Checklist, at Attachment II.

[23] *See* China AD Initiation Checklist, at Attachment II.

[24] *Id.*

[25] *Id.*

[26] *See* Volume I of the Petition, at 23–24.

[27] *Id.* at 13–15, 22–35, and Exhibits I–5 and I–11 through I–24.

[28] *See* China AD Initiation Checklist, at Attachment III, ''Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Vertical Shaft Engines Between 225cc and 999cc, and Parts thereof from the People's Republic of China'' (Attachment III).

[29] *See* Countervailing Duty Investigation Initiation Checklist: Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the People's Republic of China (China CVD Initiation Checklist), dated concurrently with this notice and on file electronically via ACCESS, at 7. Access to documents filed via ACCESS is also

Continued

version of the initiation checklist for this investigation is available on ACCESS. In accordance with section 703(b)(1) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determination no later than 65 days after the date of this initiation.

Critical Circumstances

The petitioner alleges, based on trade statistics, that there is a reasonable basis to believe or suspect that critical circumstances exist with regard to imports of vertical shaft engines from China.[30]

Section 703(e)(1) of the Act provides that if a petitioner alleges critical circumstances, Commerce will find that such circumstances exist, at any time after the date of initiation, when there is a reasonable basis to believe or suspect: (A) That ''the alleged countervailable subsidy'' is inconsistent with the Agreement on Subsidies and Countervailing Measures (SCM Agreement) of the World Trade Organization, and (B) that ''there have been massive imports of the subject merchandise over a relatively short period.'' Section 351.206(h)(2) of the Commerce's regulations provides that, generally, imports must increase by at least 15 percent during the ''relatively short period'' to be considered ''massive,'' and section 351.206(i) defines a ''relatively short period'' as normally being the period beginning on the date the proceeding begins (*i.e.,* the date the petition is filed) [31] and ending at least three months later.[32] The regulations also provide, however, that, if Commerce ''finds that importers, or exporters or producers, had reason to believe, at some time prior to the beginning of the proceeding, that a proceeding was likely,'' Commerce ''may consider a period of not less than three months from that earlier time.'' [33]

The petitioner alleges that Chinese vertical shaft engine producers benefit from numerous Chinese government subsidies, which include subsidies that are contingent upon export performance, subsidies for inputs provided for less than adequate remuneration (LTAR), tax benefits, and export incentives.[34] Specifically, the GOC supported vertical shaft engines producers and exporters through the provision of aluminum and pig iron for LTAR, GOC subsidies for the development of famous export brands and China world top brands, export credits granted under the catalogue of Chinese high-tech products for export, and the provision of land at LTAR.[35]

The petitioner also asserts that there have been massive imports of vertical shaft engines over a relatively short period. Based on the petitioner's calculation, the imports of engines in the classification that most closely approximates vertical shaft engines surged 35.7 percent between June 2019 through November 2019 against the same period in calendar year 2018.[36] The petitioner chose these base and comparison periods in order to account for seasonality and the unusual circumstances caused by the imposition of 25 percent Section 301 duties, in accordance with 19 CFR 351.206(h)(1)(ii). The petitioner asserts that, because the surge in imports constituted more than a 15 percent change, import volumes of vertical shaft engines are massive, as defined in Commerce's regulations.

The petitioner requests that the Commerce make a preliminary finding of critical circumstances within 45 days of the filing of the Petition.[37] Section 702(e) of the Act states that if ''at any time after the initiation of an investigation under this subtitle, the administering authority finds a reasonable basis to suspect that the alleged countervailable subsidy is inconsistent with the {SCM} Agreement, the administering authority may request the Commissioner of Customs to compile information on an expedited basis regarding entries of the subject merchandise.''

Taking into consideration the foregoing, we will analyze this matter further. We will monitor imports of vertical shaft engines from China and may request that U.S. Customs and Border Protection (CBP) compile information on an expedited basis regarding entries of subject merchandise.[38] If, at any time, the criteria for a finding of critical circumstances are established, we will issue a critical circumstances determination at the earliest possible date.[39]

Respondent Selection

The petitioner named 35 companies in China as producers/exporters of vertical shaft engines.[40] Commerce intends to follow its standard practice in CVD investigations and calculate company-specific subsidy rates in this investigation. In the event Commerce determines that the number of companies is large and it cannot individually examine each company based upon Commerce's resources, where appropriate, Commerce intends to select mandatory respondents based on CBP data for U.S. imports of vertical shaft engines from China during the POI under the appropriate Harmonized Tariff Schedule of the United States numbers listed in the ''Scope of the Investigation,'' in the appendix.

On February 3, 2020, Commerce released CBP data on imports of vertical shaft engines from China under administrative protective order (APO) to all parties with access to information protected by APO and indicated that interested parties wishing to comment on the CBP data must do so within three business days of the publication date of the notice of initiation of this investigation.[41] We further stated that we will not accept rebuttal comments.

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on the Commerce website at *http://enforcement.trade.gov/apo.*

Comments must be filed electronically using ACCESS. An electronically filed document must be received successfully, in its entirety, by ACCESS no later than 5:00 p.m. ET on the date noted above. Commerce intends to finalize its decisions regarding respondent selection within 20 days of publication of this notice.

Distribution of Copies of the Petition

In accordance with section 702(b)(3)(A) of the Act and 19 CFR 351.202(f), a copy of the public version of the Petition has been provided to the GOC via ACCESS.

Furthermore, to the extent practicable, Commerce will attempt to provide a copy of the public version of the Petition to each exporter named in the Petition, as provided under 19 CFR 351.203(c)(2).

available in the Central Records Unit, Room B8024 of the main Commerce building.

[30] *See* Volume IV of the Petition, at 3–6.

[31] *See* 19 CFR 351.102(b)(40) (providing that a proceeding begins on the date of the filing of a petition).

[32] *See* 19 CFR 351.206(i).

[33] *Id.*

[34] *See* Volume III of the Petition, at 11–59.

[35] *Id* at 15, 22, 39 and 56–57.

[36] *See* Volume IV of the Petition, at 6.

[37] *Id.* at 11.

[38] *See* section 702(e) of the Act.

[39] *See Change in Policy Regarding Timing of Issuance of Critical Circumstances Determinations,* 63 FR 55364 (October 15, 1998).

[40] *See* Volume I of the Petition, at Exhibit I–10.

[41] *See* Memorandum, ''Certain Vertical Shaft Engines between 225cc and 999cc, and Parts Thereof from the People's Republic of China Countervailing Duty Petition: Release of U.S. Customs and Border Protection Data,'' dated February 3, 2020.

ITC Notification

Commerce will notify the ITC of its initiation, as required by section 702(d) of the Act.

Preliminary Determinations by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petition was filed, whether there is a reasonable indication that imports of vertical shaft engines from China are materially injuring or threatening material injury to a U.S. industry.[42] A negative ITC determination will result in the investigation being terminated.[43] Otherwise, this investigation will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). Any party, when submitting factual information, must specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted[44] and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.[45] Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Please review the regulations prior to submitting factual information in this investigation.

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by Commerce. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. ET on the due date. Under certain circumstances, Commerce may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, Commerce will inform parties in a letter or memorandum of the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, standalone submission; under limited circumstances Commerce will grant untimely filed requests for the extension of time limits. Parties should review *Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting extension requests or factual information in this investigation.

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[46] Parties must use the certification formats provided in 19 CFR 351.303(g).[47] Commerce intends to reject factual submissions if the submitting party does not comply with the applicable certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. Instructions for filing such applications may be found on the Commerce website at *http://enforcement.trade.gov/apo.*

On January 22, 2008, Commerce published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Parties wishing to participate in this investigation should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed at 19 CFR 351.103(d)).

This notice is issued and published pursuant to sections 702 and 777(i) of the Act, and 19 CFR 351.203(c).

Dated: February 4, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Investigation

The merchandise covered by this investigation consists of spark-ignited, non-road, vertical shaft engines, whether finished or unfinished, whether assembled or unassembled, primarily for riding lawn mowers and zero-tum radius lawn mowers. Engines meeting this physical description may also be for other non-hand-held outdoor power equipment such as, including but not limited to, tow-behind brush mowers, grinders, and vertical shaft generators. The subject engines are spark ignition, single or multiple cylinder, air cooled, internal combustion engines with vertical power take off shafts with a minimum displacement of 225 cubic centimeters (cc) and a maximum displacement of 999cc. Typically, engines with displacements of this size generate gross power of between 6.7 kilowatts (kw) to 42 kw.

Engines covered by this scope normally must comply with and be certified under Environmental Protection Agency (EPA) air pollution controls title 40, chapter I, subchapter U, part 1054 of the Code of Federal Regulations standards for small non-road spark-ignition engines and equipment. Engines that otherwise meet the physical description of the scope but are not certified under 40 CFR part 1054 and are not certified under other parts of subchapter U of the EPA air pollution controls are not excluded from the scope of this proceeding. Engines that may be certified under both 40 CFR part 1054 as well as other parts of subchapter U remain subject to the scope of this proceeding.

For purposes of this investigation, an unfinished engine covers at a minimum a sub-assembly comprised of, but not limited to, the following components: Crankcase, crankshaft, camshaft, piston(s), and connecting rod(s). Importation of these components together, whether assembled or unassembled, and whether or not accompanied by additional components such as an oil pan, manifold, cylinder head(s), valve train, or valve cover(s), constitutes an unfinished engine for purposes of this investigation. The inclusion of other products such as spark plugs fitted into the cylinder head or electrical devices (*e.g.,* ignition modules, ignition coils) for synchronizing with the motor to supply tension current does not remove the product from the scope. The inclusion of any other components not identified as comprising the unfinished engine subassembly in a third-country does not remove the engine from the scope.

The engines subject to this investigation are typically classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings: 8407.90.1020, 8407.90.1060, and 8407.90.1080. The engine subassemblies that are subject to this investigation enter under HTSUS 8409.91.9990. Engines subject to this investigation may also enter under HTSUS 8407.90.9060 and 8407.90.9080. The

[42] *See* section 733(a) of the Act.

[43] *Id.*

[44] *See* 19 CFR 351.301(b).

[45] *See* 19 CFR 351.301(b)(2).

[46] *See* section 782(b) of the Act.

[47] *See Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

HTSUS subheadings are provided for convenience and customs purposes only, and the written description of the merchandise under investigation is dispositive.

[FR Doc. 2020–03104 Filed 2–14–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–026; C–570–027]

Certain Corrosion-Resistant Steel Products From the People's Republic of China: Negative Preliminary Determination of Circumvention Involving Guatemala

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that imports of certain corrosion-resistant steel products (CORE) completed in Guatemala are not circumventing the antidumping duty (AD) and countervailing duty (CVD) orders on CORE from the People's Republic of China (China) at this time.

DATES: Applicable February 18, 2020.

FOR FURTHER INFORMATION CONTACT: Drew Jackson, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4406.

SUPPLEMENTARY INFORMATION:

Background

On August 12, 2019, Commerce self-initiated country-wide anti-circumvention inquiries of the *China CORE Orders* [1] covering Chinese-origin hot-rolled steel (HRS) and/or cold-rolled steel (CRS) exported to various countries, including Guatemala, for completion into CORE and subsequently exported to the United States.[2] In the *Initiation Notice,* Commerce initiated the instant anti-circumvention inquiries based on available information and an analysis pursuant to section 781(b) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.225(h), to determine whether the importation of the Chinese-origin HRS or CRS substrate for completion into CORE in Guatemala and subsequent exportation of that CORE to the United States constitutes circumvention of the *China CORE Orders.*

For a complete description of the record developed since the initiation of these inquiries, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Orders

The products covered by these orders are certain flat-rolled steel products, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel- or iron-based alloys, whether or not corrugated or painted, varnished, laminated, or coated with plastics or other non-metallic substances in addition to the metallic coating. For a complete description of the scope of the orders, *see* the Preliminary Decision Memorandum.

Scope of the Anti-Circumvention Inquiries

These anti-circumvention inquiries cover CORE completed in Guatemala from HRS or CRS substrate input manufactured in China and subsequently exported from Guatemala to the United States.

Methodology

Commerce is conducting these anti-circumvention inquiries in accordance with section 781(b) of the Act and 19 CFR 351.225(h). For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

Preliminary Finding

As detailed in the Preliminary Decision Memorandum, we preliminarily determine that Ternium Internacional Guatemala S.A. is neither producing CORE from Chinese substrate in Guatemala nor exporting CORE incorporating Chinese substrate to the United States at present, or at any point recent enough to support the concerns which served as the basis for the initiation of these inquiries, and thus action is not appropriate to address circumvention of the *China CORE Orders,* at this time. Accordingly, Commerce is making a preliminary negative finding of circumvention of the *China CORE Orders.*

Verification

As provided in 19 CFR 351.307, Commerce intends to verify information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the final verification report is issued in these anti-circumvention inquiries, unless the Secretary alters the time limit. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[4] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in these anti-circumvention inquiries are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date

[1] *See Certain Corrosion-Resistant Steel Flat Products from India, Italy, the People's Republic of China, the Republic of Korea, and Taiwan: Amended Final Affirmative Antidumping Duty Determination for India and Taiwan, and Antidumping Duty Orders,* 81 FR 48390 (July 25, 2016); *see also Certain Corrosion-Resistant Steel Products from India, Italy, Republic of Korea, and the People's Republic of China: Countervailing Duty Order,* 81 FR 48387 (July 25, 2016) (collectively, *China CORE Orders*).

[2] The notice of initiation subsequently published in the **Federal Register** on August 21, 2019. *See Corrosion-Resistant Steel Products from the People's Republic of China: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders,* 84 FR 43585 (August 21, 2019) (*Initiation Notice*) and accompanying Memorandum, ''Certain Corrosion-Resistant Steel Products from the People's Republic of China: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders,'' dated August 12, 2019.

[3] *See* Memorandum, ''Preliminary Decision Memorandum for the Anti-Circumvention Inquiries Involving Guatemala of the Antidumping and Countervailing Duty Orders on Certain Corrosion-Resistant Steel Products from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Notification to Interested Parties

This determination is issued and published in accordance with section 781(b) of the Act and 19 CFR 351.225(f).

Dated: February 7, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Orders
IV. Scope of the Anti-Circumvention Inquiries
V. Period of Inquiries
VI. Statutory Framework
VII. Anti-Circumvention Determination
VIII. Verification
IX. Recommendation

[FR Doc. 2020–03140 Filed 2–14–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–026; C–570–027]

Certain Corrosion-Resistant Steel Products From the People's Republic of China: Affirmative Preliminary Determination of Circumvention Involving the United Arab Emirates

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that imports of certain corrosion-resistant steel products (CORE), completed in the United Arab Emirates (the UAE) using hot-rolled steel (HRS) and/or cold-rolled steel (CRS) flat products manufactured in the People's Republic of China (China), are circumventing the antidumping duty (AD) and countervailing duty (CVD) orders on CORE from China.

DATES: Applicable February 18, 2020.

FOR FURTHER INFORMATION CONTACT: Eli Lovely, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1593.

SUPPLEMENTARY INFORMATION:

Background

On August 12, 2019, Commerce self-initiated country-wide anti-circumvention inquiries of the *China CORE Orders* [1] covering Chinese-origin HRS and/or CRS exported to various countries, including the UAE, for completion into CORE and subsequently exported to the United States.[2] In the *Initiation Notice,* Commerce initiated the instant anti-circumvention inquiries based on available information and an analysis pursuant to section 781(b) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.225(h), to determine whether the importation of the Chinese-origin HRS or CRS substrate for completion into CORE in the UAE and subsequent exportation of that CORE to the United States constitutes circumvention of the *China CORE Orders.*

For a complete description of the record developed since the initiation of these inquiries, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Orders

The products covered by these orders are certain flat-rolled steel products, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel- or iron-based alloys, whether or not corrugated or painted, varnished, laminated, or coated with plastics or other non-metallic substances in addition to the metallic coating. For a complete description of the scope of the orders, *see* the Preliminary Decision Memorandum.

Scope of the Anti-Circumvention Inquiries

These anti-circumvention inquiries cover CORE completed in the UAE from HRS or CRS substrate input manufactured in China and subsequently exported from the UAE to the United States (merchandise subject to these inquiries).

Methodology

Commerce is conducting these anti-circumvention inquiries in accordance with section 781(b) of the Act and 19 CFR 351.225(h). Because certain interested parties did not cooperate to the best of their abilities in responding to Commerce's requests for information, we have based parts of our preliminary determination on the facts available, with adverse inferences, pursuant to sections 776(a) and (b) of the Act. For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

Preliminary Finding

As detailed in the Preliminary Decision Memorandum, we preliminarily determine that CORE completed in the UAE from HRS and/or CRS substrate sourced from China is circumventing the *China CORE Orders.* We therefore preliminarily determine that it is appropriate to include this merchandise within the *China CORE Orders* and to instruct U.S. Customs and Border Protection (CBP) to suspend liquidation of any entries of CORE from

[1] *See Certain Corrosion-Resistant Steel Flat Products from India, Italy, the People's Republic of China, the Republic of Korea, and Taiwan: Amended Final Affirmative Antidumping Duty Determination for India and Taiwan, and Antidumping Duty Orders,* 81 FR 48390 (July 25, 2016); *see also Certain Corrosion-Resistant Steel Products from India, Italy, Republic of Korea, and the People's Republic of China: Countervailing Duty Order,* 81 FR 48387 (July 25, 2016) (collectively, *China CORE Orders*).

[2] The notice of initiation subsequently published in the **Federal Register** on August 21, 2019. *See Corrosion-Resistant Steel Products from the People's Republic of China: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders,* 84 FR 43585 (August 21, 2019) (*Initiation Notice*) and accompanying Memorandum, ''Certain Corrosion-Resistant Steel Products from the People's Republic of China: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders,'' dated August 12, 2019.

[3] *See* Memorandum, ''Preliminary Decision Memorandum for the Anti-Circumvention Inquiry Involving the United Arab Emirates of the Antidumping and Countervailing Duty Orders on Certain Corrosion-Resistant Steel Products from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

the UAE produced from HRS and/or CRS from China.

Suspension of Liquidation

As stated above, Commerce has made a preliminary affirmative determination that imports of CORE complete in the UAE, using HRS and/or CRS flat products manufactured in China, are circumventing the *China CORE Orders.* In accordance with 19 CFR 351.225(l)(2), Commerce will direct CBP to suspend liquidation and to require a cash deposit of estimated duties on unliquidated entries of CORE produced in the UAE, as appropriate, that were entered, or withdrawn from warehouse, for consumption on or after August 12, 2019, the date of initiation of the anti-circumvention inquiries. The suspension of liquidation instructions will remain in effect until further notice.

CORE produced in the UAE from HRS and/or CRS that is not of Chinese origin is not subject to these inquiries. However, imports of such merchandise are also subject to certification requirements, and cash deposits may be required if the certification requirements are not satisfied. Accordingly, if an importer imports CORE from the UAE and claims that the CORE was not produced from HRS and/or CRS substrate manufactured in China, the importer and exporter are required to meet the certification and documentation requirements described in Appendices II, III, and IV, in order for cash deposits pursuant to the *China CORE Orders* not to be required.

In the situation where no certification is provided for an entry, and AD/CVD orders from China therefore potentially apply to that entry, Commerce intends to instruct CBP to suspend liquidation of the entry and collect cash deposits at the rates applicable to the *China CORE Orders* (*i.e.,* the AD rate established for the China-wide entity (199.43 percent) and the CVD rate established for the China all-others rate (39.05 percent)).[4]

Commerce preliminarily determines that the following company is not eligible for the certification process: Asian Ispat FZ LLC. Additionally, exporters are not eligible to certify shipments of merchandise produced by Asian Ispat FZ LLC. Further, importers of CORE from the UAE that is produced and/or exported by this ineligible company are similarly ineligible for the certification process with regard to those imports.

Verification

As provided in 19 CFR 351.307, Commerce intends to verify information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last final verification report is issued in these anti-circumvention inquiries, unless the Secretary alters the time limit. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[5] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in these anti-circumvention inquiries are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

International Trade Commission Notification

Commerce, consistent with section 781(e) of the Act, has notified the U.S. International Trade Commission (ITC) of this preliminary determination to include the merchandise subject to these anti-circumvention inquiries within the *China CORE Orders.* Pursuant to section 781(e) of the Act, the ITC may request consultations concerning Commerce's proposed inclusion of the merchandise subject to these inquiries. If, after consultations, the ITC believes that a significant injury issue is presented by the proposed inclusion, it will have 60 days from the date of notification by Commerce to provide written advice.

Notification to Interested Parties

This determination is issued and published in accordance with section 781(b) of the Act and 19 CFR 351.225(f).

Dated: February 7, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

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II. Background
III. Scope of the Orders
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V. Period of Inquiries
VI. Surrogate Countries and Methodology for Valuing Inputs From China
VII. Statutory Framework
VIII. Use of Facts of Available With an Adverse Inference
IX. Anti-Circumvention Determination
X. Country-Wide Determination
XI. Certification for Not Using Chinese-Origin HRS and/or CRS
XII. Verification
XIII. Recommendation

Appendix II

Certification Requirements

If an importer imports certain corrosion-resistant steel products (CORE) from the UAE and claims that the CORE was not produced from hot-rolled steel and/or cold-rolled steel substrate (substrate) manufactured in the People's Republic of China (China), the importer is required to complete and maintain the importer certification attached hereto as Appendix III and all supporting documentation. Where the importer uses a broker to facilitate the entry process, it should obtain the entry number from the broker. Agents of the importer, such as brokers, however, are not permitted to make this certification on behalf of the importer.

The exporter is required to complete and maintain the exporter certification, attached as Appendix III, and is further required to provide the importer a copy of that certification and all supporting documentation.

For shipments and/or entries on or after August 12, 2019 through March 7, 2020, for which certifications are required, importers and exporters should complete the required certification within 30 days of the publication of this notice in the **Federal Register**. Accordingly, where appropriate, the relevant bullet in the certification should be edited to reflect that the certification was completed within the time frame specified above. For example, the bullet in the importer certification that reads: ''This certification was completed at or prior to the time of Entry,'' could be edited as follows: ''The imports referenced herein entered before March 8, 2020. This certification was completed on mm/dd/yyyy, within 30 days of the **Federal Register** notice publication of the preliminary determination of circumvention.'' Similarly, the bullet in the

[4] *See China CORE Orders.*

[5] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

exporter certification that reads, ''This certification was completed at or prior to the time of shipment,'' could be edited as follows: ''The shipments/products referenced herein shipped before March 8, 2020. This certification was completed on mm/dd/yyyy, within 30 days of the **Federal Register** notice publication of the preliminary determination of circumvention. For such entries/shipments, importers and exporters each have the option to complete a blanket certification covering multiple entries/shipments, individual certifications for each entry/shipment, or a combination thereof.

For shipments and/or entries on or after March 7, 2020, for which certifications are required, importers should complete the required certification at or prior to the date of Entry and exporters should complete the required certification and provide it to the importer at or prior to the date of shipment.

The importer and UAE exporter are also required to maintain sufficient documentation supporting their certifications. The importer will not be required to submit the certifications or supporting documentation to U.S. Customs and Border Protection (CBP) as part of the entry process at this time. However, the importer and the exporter will be required to present the certifications and supporting documentation, to Commerce and/or CBP, as applicable, upon request by the respective agency. Additionally, the claims made in the certifications and any supporting documentation are subject to verification by Commerce and/or CBP. The importer and exporter are required to maintain the certifications (the importer must retain both certifications) and supporting documentation for the later of: (1) A period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries.

In the situation where no certification is provided for an entry, Commerce intends to instruct CBP to suspend liquidation of the entry and collect cash deposits at the rate applicable to the *CORE China Orders* (*i.e.,* the AD rate established for the China-wide entity (199.43 percent) and the CVD rate established for China all-others rate (39.05 percent)).

Appendix III

Exporter Certification

I hereby certify that:

• My name is {COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF EXPORTING COMPANY}, located at {ADDRESS OF EXPORTING COMPANY};

• I have direct personal knowledge of the facts regarding the production and exportation of the corrosion resistant steel products identified below. ''Direct personal knowledge'' refers to facts the certifying party is expected to have in its own books and records. For example, an exporter should have direct personal knowledge of the producer's identity and location.

• The corrosion resistant steel products covered by this certification were produced by {NAME OF PRODUCING COMPANY}, located at {ADDRESS OF PRODUCING COMPANY}; *for each additional company, repeat:* {NAME OF PRODUCING COMPANY}, located at {ADDRESS OF PRODUCING COMPANY}

• The corrosion resistant steel products produced in the UAE were not manufactured using hot-rolled steel and/or cold-rolled steel substrate from China;

• This certification applies to the following sales:

Producer	Invoice No.	Invoice line item No.

• The corrosion resistant steel products covered by this certification were sold to {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}.

• The corrosion resistant steel products covered by this certification were shipped to {NAME OF PARTY TO WHOM MERCHANDISE WAS SHIPPED}, located at {ADDRESS OF SHIPMENT}.

• I understand that {NAME OF EXPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, mill certificates, production records, invoices, etc.) for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in the United States courts regarding such entries;

• I understand that {NAME OF EXPORTING COMPANY} must provide a copy of this Exporter Certification to the U.S. importer by the time of shipment;

• I understand that {NAME OF EXPORTING COMPANY} is required to provide a copy of this certification and supporting records, upon request, to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce);

• I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce;

• I understand that failure to maintain the required certification, and/or failure to substantiate the claims made herein, and/or failure to allow CBP and/or Commerce to verify the claims made herein, may result in a de facto determination that all sales to which this certification applies are within the scope of the antidumping/countervailing duty order on corrosion resistant steel products from China. I understand that such finding will result in:

○ Suspension of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met; and

○ the requirement that the importer post applicable antidumping duty and/or countervailing duty cash deposits (as appropriate) equal to the rates as determined by Commerce;

○ the revocation of {NAME OF EXPORTING COMPANY}'s privilege to certify future exports of corrosion resistant steel products from the UAE as not manufactured using hot-rolled steel and/or cold-rolled steel substrate from China.

• This certification was completed at or prior to the time of shipment; and

• I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government.

Signature

NAME OF COMPANY OFFICIAL
TITLE
DATE

Appendix IV

Importer Certification

I hereby certify that:

• My name is {IMPORTING COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF IMPORTING COMPANY}, located at {ADRESS OF IMPORTING COMPANY}.

• I have direct personal knowledge of the facts regarding the importation into the Customs territory of the United States of the corrosion resistant steel products produced in the UAE that entered under entry number(s), identified below, and which are covered by this certification. ''Direct personal knowledge'' refers to facts the certifying party is expected to have in its own records. For example, the importer should have direct personal knowledge of the importation of the product (*e.g.,* the name of the exporter) in its records;

• The corrosion resistant steel products covered by this certification were exported by {NAME OF EXPORTING COMPANY}, located at {ADDRESS OF EXPORTING COMPANY}.

If the importer is acting on behalf of the first U.S. customer, complete this paragraph:

• The corrosion resistant steel products covered by this certification were imported by {NAME OF IMPORTING COMPANY} on behalf of {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}.

• The corrosion resistant steel products covered by this certification were shipped to {NAME OF PARTY TO WHOM MERCHANDISE WAS FIRST SHIPPED IN THE UNITED STATES}, located at {ADDRESS OF SHIPMENT}.

• I have personal knowledge of the facts regarding the production of the corrosion resistant steel products identified below.

''Personal knowledge'' includes facts obtained from another party, (*e.g.,* correspondence received by the importer (or exporter) from the producer regarding the country of manufacture of the imported products);

• The corrosion resistant steel products covered by this certification were produced by {NAME OF PRODUCING COMPANY}, located at {ADDRESS OF PRODUCING COMPANY}; *for each additional company, repeat:* {NAME OF PRODUCING COMPANY}, located at {ADDRESS OF PRODUCING COMPANY}.

• The corrosion resistant steel products covered by this certification were not manufactured using hot-rolled steel and/or cold-rolled steel substrate from China.

• This certification applies to the following entries:

Producer	Entry summary No.	Entry summary line item No.	Invoice No.	Invoice line item No.

• I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, mill certificates, production records, invoices, etc.) for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in the United States courts regarding such entries;

• I understand that {NAME OF IMPORTING COMPANY} is required to provide this certification and supporting records, upon request, to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce);

• I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of the exporter's certification (attesting to the production and/or export of the imported merchandise identified above), and any supporting records provided by the exporter to the importer, for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries;

• I understand that {NAME OF IMPORTING COMPANY} is required to maintain and, upon request, provide a copy of the exporter's certification and any supporting records provided by the exporter to the importer, to CBP and/or Commerce;

• I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce;

• I understand that failure to maintain the required certifications, and/or failure to substantiate the claims made herein, and/or failure to allow CBP and/or Commerce to verify the claims made herein, may result in a de facto determination that all entries to which this certification applies are within the scope of the antidumping/countervailing duty order on corrosion resistant steel products from China. I understand that such finding will result in:

○ Suspension of liquidation of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met; and;

○ the requirement that the importer post applicable antidumping duty and/or countervailing duty cash deposits (as appropriate) equal to the rates determined by Commerce;

the revocation of {NAME OF IMPORTING COMPANY}'s privilege to certify future imports of corrosion resistant steel products from the UAE as not manufactured using hot-rolled steel and/or cold-rolled steel substrate from China.

• I understand that agents of the importer, such as brokers, are not permitted to make this certification;

• This certification was completed at or prior to the time of Entry; and

• I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government.

Signature

NAME OF COMPANY OFFICIAL
TITLE
DATE

[FR Doc. 2020–03143 Filed 2–14–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–026; C–570–027]

Certain Corrosion-Resistant Steel Products From the People's Republic of China: Negative Preliminary Determination of Circumvention Involving South Africa

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that imports of certain corrosion-resistant steel products (CORE), completed in South Africa are not circumventing the antidumping duty (AD) and countervailing duty (CVD) orders on CORE from the People's Republic of China (China) at this time.

DATES: Applicable February 18, 2020.

FOR FURTHER INFORMATION CONTACT: Laura Griffith, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6430.

SUPPLEMENTARY INFORMATION:

Background

On August 12, 2019, Commerce self-initiated country-wide anti-circumvention inquiries of the *China CORE Orders* [1] covering Chinese-origin hot-rolled steel (HRS) and/or cold-rolled steel (CRS) exported to various countries, including South Africa, for completion into CORE and subsequently exported to the United States.[2] In the *Initiation Notice,* Commerce initiated the instant anti-circumvention inquiries based on available information and an analysis pursuant to section 781(b) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.225(h), to determine whether the importation of the Chinese-origin HRS or CRS substrate for completion into CORE in South Africa and subsequent exportation of that CORE to the United States constitutes circumvention of the *China CORE Orders.*

For a complete description of the record developed since the initiation of these inquiries, *see* the Preliminary Decision Memorandum.[3] A list of topics

[1] *See Certain Corrosion-Resistant Steel Flat Products from India, Italy, the People's Republic of China, the Republic of Korea, and Taiwan: Amended Final Affirmative Antidumping Duty Determination for India and Taiwan, and Antidumping Duty Orders,* 81 FR 48390 (July 25, 2016); *see also Certain Corrosion-Resistant Steel Products from India, Italy, Republic of Korea, and the People's Republic of China: Countervailing Duty Order,* 81 FR 48387 (July 25, 2016) (collectively, *China CORE Orders*).

[2] The notice of initiation subsequently published in the **Federal Register** on August 21, 2019. *See Corrosion-Resistant Steel Products from the People's Republic of China: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders,* 84 FR 43585 (August 21, 2019) (*Initiation Notice*) and accompanying Memorandum, ''Certain Corrosion-Resistant Steel Products from the People's Republic of China: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders,'' dated August 12, 2019.

[3] *See* Memorandum, ''Preliminary Decision Memorandum for the Anti-Circumvention Inquiries Involving the Republic of South Africa of the Antidumping and Countervailing Duty Orders on Certain Corrosion-Resistant Steel Products from the People's Republic of China,'' dated concurrently

included in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the China CORE Orders

The products covered by these orders are certain flat-rolled steel products, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel- or iron-based alloys, whether or not corrugated or painted, varnished, laminated, or coated with plastics or other non-metallic substances in addition to the metallic coating. For a complete description of the scope of the orders, *see* the Preliminary Decision Memorandum.

Scope of the Anti-Circumvention Inquiries

These anti-circumvention inquiries cover CORE completed in South Africa from HRS or CRS substrate input manufactured in China and subsequently exported from South Africa to the United States.

Methodology

Commerce is conducting these anti-circumvention inquiries in accordance with section 781(b) of the Act and 19 CFR 351.225(h). For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

Preliminary Finding

As detailed in the Preliminary Decision Memorandum, we preliminarily determine that CORE produced in South Africa and exported to the United States is not being completed from Chinese-origin HRS or CRS substrate at present, or at any point recent enough to support the concerns which served as the basis for the initiation of these inquiries, and thus, action is not appropriate to address circumvention of the *China CORE Orders* at this time. Accordingly, Commerce is making a preliminary negative finding of circumvention of the *China CORE Orders.*

Verification

As provided in 19 CFR 351.307, Commerce intends to verify information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the final verification report is issued in these anti-circumvention inquiries, unless the Secretary alters the time limit. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[4] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in these anti-circumvention inquiries are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Notification to Interested Parties

This determination is issued and published in accordance with section 781(b) of the Act and 19 CFR 351.225(f).

Dated: February 7, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Orders
IV. Scope of the Anti-Circumvention Inquiries
V. Period of Inquiries
VI. Statutory Framework
VII. Anti-Circumvention Determination
VIII. Verification
IX. Recommendation

[FR Doc. 2020–03142 Filed 2–14–20; 8:45 am]

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with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; West Coast Region Groundfish Trawl Fishery Electronic Monitoring Program

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before April 20, 2020.

ADDRESSES: Direct all written comments to Adrienne Thomas, Government Information Specialist, NOAA, 151 Patton Avenue, Room 159, Asheville, NC 28801 (or via the internet at *PRAcomments@doc.gov*). All comments received are part of the public record. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection

instrument and instructions should be directed to Jahnava Duryea, National Marine Fisheries Service, California Central Valley Office, 650 Capital Mall, Suite 5–100, Sacramento, CA 95814, (916) 930–3725 or via email at *jahnava.duryea@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a revision and extension of a currently approved information collection.

The National Marine Fisheries Service (NMFS) published a final rule on June 28, 2019 (84 FR 31146), to implement an electronic monitoring (EM) program for two sectors of the limited entry trawl fishery, consistent with the Magnuson-Stevens Fishery Conservation and Management Act (MSA) and the Pacific Coast Groundfish Fishery Management Plan (FMP). The action allows catcher vessels in the Pacific whiting fishery and fixed gear vessels in the shorebased Individual Fishing Quota (IFQ) fishery to use EM in place of observers to meet the requirements of the Trawl Rationalization Program for 100-percent at-sea observer coverage. This action is necessary to increase operational flexibility and reduce monitoring costs for vessels in the trawl fishery by providing an alternative to observers.

Under this collection, some catcher vessels will have the option to use EM in place of observers to reduce total fleet monitoring costs to levels sustainable for the fleet and agency and meet the requirements for 100-pecent observer coverage at-sea. In place of an observer documenting discards onboard, captains would report estimates of their own discards on a logbook and submit them to NMFS. NMFS would use the discards reported on the logbook to debit allocations in the Vessel Accounting System (VAS) and North Pacific Database Program (NorPac). They would also install and carry and EM system to capture fishing activities at-sea. Following the trip, an analyst would review the video and report estimates of discards of allocated species to NMFS to use to audit the validity of the logbook estimates. The EM data would also be used to monitor compliance with the requirements of the catch share program. In this way, logbooks and EM systems would be used in tandem in place of observers to meet the objectives of 100-percent at-sea monitoring of the catch share program.

Vessel operators would be required to submit a logbook reporting their discards of IFQ species. NMFS would use the logbook data to debit discards of IFQ species from IFQs and cooperative allocations, and use the EM data to audit the logbook data. EM data would also be used to monitor compliance with the requirements of the catch share program. Vessel operators would be required to submit a logbook reporting their discards of IFQ species.

New requirements being added to this collection include:

EM Service Providers will be required to submit catch reports and feedback reports, and store EM data and other records.

Vessel Owners will be required to obtain services from an NMFS-permitted EM service provider to analyze and store EM data, and report it to NMFS.

II. Method of Collection

Information that would be required is specified in the regulations at 50 CFR 660.603(b)(1) and 660.604(b)(1) in the final rule 0648–BF52. Information is collected by mail, electronically, and by phone by the NMFS West Coast Region Fisheries Permit Office.

The following information is collected by mail: *EM service providers:* EM service provider application and renewals; EM service plan and any subsequent changes to plan; submission of two EM units and standard operating procedures (SOPs), if requested by NMFS; EM service provider appeals; and EM data storage downloaded to hard drive and shipped (not required until 2021). *Vessel owners:* Initial application; final application (EM system certification, tentative fishing plan, vessel monitoring plan); changes to vessel monitoring plan; and EM system certification; *Vessel operators:* Federal discard logbook for each landing; and hard drive submission.

The following information is collected electronically: *EM service providers:* EM provider reports of technical assistance requests, harassment and intimidation, and non-compliance; catch reports, feedback reports, and EM data storage uploaded to a secure website (not required until 2021); *Vessel operators:* One-time online EM training provided by NMFS; and federal discard logbook (if authorized in writing by NMFS).

The following information may be collected by phone: *EM service providers:* follow-up debriefings with EM provider employees regarding technical assistance, harassment and intimidation, or non-compliance; and ongoing program and technical support.

III. Data

OMB Control Number: 0648–0785.

Form Number(s): None.

Type of Review: Regular (revision and extension of a current approved collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 146 (5 EM service providers, 58 vessel owners, 83 vessel operators).

Estimated Time per Response: EM service providers: Application (application form, EM service plan, submission of EM units)—5 hours; application renewals (biennial)—1 hour; EM service provider appeal—4 hours; EM service plan changes—2 hours; EM system certification—30 minutes; reports (technical assistance—40 minutes, harassment and intimidation—1 hour, compliance reports—20 minutes, catch reports—15 minutes, feedback to vessel—10 minutes, data storage—15 minutes); debrief of EM staff—2 hours 45 minutes. *Vessel owners:* Initial application—30 minutes; final application (updated application, EM system certification, tentative fishing plan, vessel monitoring plan)—8 hours 40 minutes; changes to vessel monitoring plan—1 hour; annual EM authorization renewal—30 minutes. *Vessel operators:* One-time online EM training provided by NMFS 1 hour 30 minutes; federal discard logbook for each landing; hard drive submission—10 minutes.

Estimated Total Annual Burden Hours: 7,727.

Estimated Total Annual Cost to Public: $1,721,073.

IV. Request for Comments

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 (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.

Sheleen Dumas,

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

[FR Doc. 2020–03111 Filed 2–14–20; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA047]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's (Council) Scientific and Statistical Committee (SSC) of the will hold a meeting.

DATES: The meeting will be held on Tuesday, March 10, 2020, starting at 1 p.m. and continue through 12:30 p.m. on Wednesday, March 11, 2020. See **SUPPLEMENTARY INFORMATION** for agenda details.

ADDRESSES: The meeting will take place at the Royal Sonesta Harbor Place, 550 Light Street, Baltimore, MD 21202; telephone: (410) 234–0550.

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; website: *www.mafmc.org*.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to make acceptable biological catch (ABC) recommendations for golden tilefish for the 2021 fishing year and interim recommendations for the 2022 fishing year based on information in the 2020 data update. The SSC will also review the most recent survey and fishery data and the previously recommended 2021 ABC for blueline tilefish. The SSC will also review and provide feedback on the most recent Mid-Atlantic State of the Ecosystem report and other Ecosystem Approach to Fisheries Management (EAFM) related activities. The SSC and staff from the NMFS Marine Recreational Information Program (MRIP) will have an open discussion and question and answer session regarding the recently implemented changes to the recreational data collection program with a focus on specific implications to Mid-Atlantic stocks. The SSC will discuss the 2020–2024 stock assessment schedule, recent changes to the Mid-Atlantic Council's risk policy, and receive an update from the *Illex* workgroup. In addition, the SSC may take up any other business as necessary.

A detailed agenda and background documents will be made available on the Council's website (*www.mafmc.org*) prior to the meeting.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: February 12, 2020.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–03137 Filed 2–14–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–T–2020–0007]

Privacy Act of 1974; System of Records

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of a new system of records.

SUMMARY: Pursuant to the Privacy Act of 1974 and the Office of Management and Budget (OMB) Circular A–108, the United States Patent and Trademark Office (USPTO) hereby gives notice it has established a new system of records titled COMMERCE/USPTO–26, Trademark Application and Registration Records. The USPTO proposes to establish this system of records to manage trademark application and registration records.

DATES: To be considered, written comments must be submitted on or before March 19, 2020. This new system of records will become effective on February 18, 2020, with routine uses becoming effective on March 19, 2020.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Email: SORN@USPTO.gov.* Include ''Privacy Act USPTO–26 comment'' in the subject line of the message.
- *Federal Rulemaking Portal: http://www.regulations.gov.*
- *Mail:* Trademark Portfolio Manager, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Eunice Wang, Trademark Portfolio Manager, Office of the Chief Information Officer, USPTO, by mail to P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–8872; or by email to *TrademarkAssistanceCenter@uspto.gov* with ''Trademark Application and Registration Records'' in the subject line.

SUPPLEMENTARY INFORMATION: The USPTO is giving notice of a proposed new system of records that is subject to the Privacy Act of 1974. The USPTO is the federal agency responsible for registering trademarks, and this system of records would collect and maintain information related to trademark applications and registrations, including on trademark applicants and their authorized representatives, to carry out the USPTO's duties.

The Privacy Act requires each agency that proposes to establish a system of records to provide adequate advance notice of any such proposal to the Office of Management and Budget (OMB), the Committee on Oversight and Government Reform of the House of Representatives, and the Committee on Homeland Security and Governmental Affairs of the Senate (5 U.S.C. 552a(r)). The purpose of providing the advance notice to OMB and Congress is to permit an evaluation of the potential effect of the proposal on the privacy and other rights of individuals. The USPTO filed a report describing the new system of records covered by this notice with the Chair of the Senate Committee on Homeland Security and Governmental Affairs, the Chair of the House Committee on Oversight and Government Reform, and the Deputy Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), on [insert date of letters].

SYSTEM NAME AND NUMBER:

Trademark Application and Registration Records, COMMERCE/USPTO–26.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

United States Patent and Trademark Office, 600 Dulany Street, Alexandria, VA 22313.

SYSTEM MANAGER(S):

Trademark Portfolio Manager, Office of the Chief Information Officer, United States Patent and Trademark Office, Alexandria, VA 22313–1450, or by

email to *TrademarkAssistanceCenter@uspto.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

35 U.S.C. 2 and 15 U.S.C. 1051–1141n.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system of records is to carry out the duties of the USPTO to issue federal trademark registrations and maintain a register of trademarks. The system allows the USPTO to collect and maintain records generated as customers apply for and prosecute a trademark application and maintain a trademark registration.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Applicants for trademark registration, registrants, and legal and other authorized representatives for such applicants and registrants.

CATEGORIES OF RECORDS IN THE SYSTEM:

All categories of records may include the name, citizenship, domicile, email address, postal address, and telephone number of the trademark applicant, registrant, and applicant's or registrant's legal or other authorized representative(s), an attorney's law firm or company affiliation and professional licensing information, and other information pertaining to an applicant's or registrant's activities in connection with the applied-for or registered mark. Records in this system include trademark applications, applicant and registrant declarations, office actions, registration certificates, and correspondence generated in the course of the prosecution of a trademark application or maintenance of a trademark registration.

RECORD SOURCE CATEGORIES:

Information in this system of records is derived from records developed during the prosecution of a trademark application or the maintenance of a trademark registration and, thus, the information may come from the trademark applicant, registrant, and applicant's or registrant's legal or other authorized representative.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. *Public Disclosure*—Records in this system of records are available for public inspection, except as of December 21, 2019, the USPTO will not make publicly available the address provided in the ''Domicile Address'' field on trademark forms. The USPTO will continue to make postal addresses provided for mark owners on trademark forms available for public inspection. Postal and domicile addresses can be different, but when a mark owner elects to provide the same address for both the postal and domicile address, that address will still be available for public inspection. Individuals may also request domicile addresses provided before December 21, 2019, or otherwise present in this system of records, not be made available for public inspection. The information in this system is used by the Agency and the public for a variety of business purposes related to determining eligibility of a mark for federal registration and enforcing trademark rights. The information is available at USPTO facilities and can also be accessed and downloaded at the USPTO's website.

2. *Foreign Entity Disclosure*—A record in this system of records may be disclosed to a foreign entity (foreign government or international organization) to satisfy requirements for the processing of an application for a foreign trademark registration or an international trademark registration.

3. *Professional Organizations or Associations*—A record in this system of records may be disclosed to professional organizations or associations with which individuals covered by this system of records may be affiliated, such as state bar disciplinary authorities, to meet their responsibilities in connection with the administration and maintenance of standards of conduct and discipline.

4. *Audit Disclosure*—A record from this system of records may be disclosed to an agency, organization, or individual for the purpose of performing an audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to USPTO officers and employees.

5. *Governments Disclosure*—A record from this system of records may be disclosed to a federal, state, local, or international agency, in response to its request, in connection with (1) the assignment, hiring, or retention of an individual, (2) the issuance of a security clearance, (3) the letting of a contract, or (4) the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

6. *Law Enforcement and Investigation*—A record in this system of records may be disclosed to a Federal, state, local, or foreign agency or other appropriate entity where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by (1) general statute or particular program statute or contract, (2) rule, regulation, or order issued pursuant thereto, or (3) the necessity to protect an interest of the Agency. The agency receiving the record(s) must be charged with the responsibility of investigating or prosecuting such violations or with enforcing or implementing the statute, rule, regulation, or order issued pursuant thereto, or protecting the interest of the Agency.

7. *Non-Federal Personnel*—A record in this system of records may be disclosed to contractors, agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other work assignment for the Agency who have need for information from the system of records: (1) In the course of operating or administrating the system of records; (2) In the course of fulfilling an agency function, but only to the extent necessary to fulfill that function; or (3) In order to fulfill their contract(s), but who do not operate the system of records within the meaning of 5 U.S.C. 552a(m).

8. *Record Informational Inquiries*—A record in this system of records may be disclosed to a Federal, state, local, or international agency, maintaining civil, criminal, or other relevant enforcement information or other pertinent information, such as current licenses, if necessary to obtain information relevant to an Agency decision concerning (1) the assignment, hiring, or retention of an individual, (2) the issuance of a security clearance, (3) the letting of a contract, or (4) the issuance of a license, grant, or other benefit.

9. *Data Breach Notification*—A record in this system of records may be disclosed to appropriate agencies, entities, and persons when (1) the USPTO suspects or has confirmed that there has been a breach of the system of records; (2) USPTO has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, USPTO (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and person is reasonably necessary to assist in connection with USPTO's efforts to respond to the suspected or confirmed

breach or to prevent, minimize, or remedy such harm.

10. *Data Breach Assistance*—A record in this system of records may be disclosed to another Federal agency or Federal entity when the Agency determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

11. *Adjudication and Litigation*—A record in this system of records may be disclosed to a court, magistrate, or administrative tribunal during the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations.

12. *Department of Justice Litigation*—A record in this system of records may be disclosed to any component of the Department of Justice for the purpose of representing the Agency, or any employee of the Agency, in pending or potential litigation to which the record is pertinent.

13. *Freedom of Information Act Assistance from Department of Justice*—A record in this system of records may be disclosed to the Department of Justice, in connection with determining whether disclosure thereof is required by the Freedom of Information Act (5 U.S.C. 552).

14. *Office of Personnel Management*—A record in this system of records may be disclosed to the Office of Personnel Management (OPM) for personnel research purposes, as a data source for management information, for the production of summary descriptive statistics and analytical studies in support of the function for which the records are collected and maintained, or for related manpower studies.

15. *Congressional Inquiries*—A record in this system of records may be disclosed to a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

16. *National Archives and Records Administration*—A record in this system of records may be disclosed to the Administrator of the National Archives and Records Administration (NARA), or said administrator's designee, during an inspection of records conducted by NARA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with NARA regulations governing inspection of records for this purpose, and any other relevant directive. Such disclosure shall not be used to make determinations about individuals.

17. *Office of Management and Budget*—A record in this system of records may be disclosed to the Office of Management and Budget (OMB), in connection with the review of private relief legislation as set forth in OMB Circular No. A–19 at any stage of the legislative coordination and clearance process.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

USPTO stores the records on electronic storage media, paper records in file folders, and microfilm.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by mark, application serial number, filing date, registration number, registration date, name of the owner, name of the attorney of record, and other identifiers in the system.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records retention and disposal is performed in accordance with the USPTO Records Control Schedule N1–241–06–2:2 or N1–241–06–2:3 (Trademark Case File Records and Related Indexes). Trademark application and case files meeting certain selection criteria (2:2) are permanent records and transferred to NARA six years after the registrations are cancelled, expired, or go abandoned. Non-selected trademark application and case files (2:3) are temporary records destroyed two years after trademark registrations are cancelled, expired, or go abandoned.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records are maintained in areas accessible only to authorized personnel in buildings protected by security guards. The electronic records stored in systems can be accessed for maintenance only by authorized personnel. Personally and Business identifiable information stored in systems are safeguarded and protected in conformance with all Federal statutory and OMB guidance requirements. The hosting facility is supported by 24/7 onsite hosting and network monitoring by trained technical staff.

RECORD ACCESS PROCEDURES:

Requests from individuals should be submitted as stated in the notification section below.

CONTESTING RECORD PROCEDURES:

The general provisions for access and/or contesting information by the individual concerned appear in 37 CFR 102 subpart B. Requests from individuals should be submitted as stated in the notification section below.

NOTIFICATION PROCEDURES:

Information about the records contained in this system may be obtained by sending a signed request to the system manager at the address above or to the address provided in 37 CFR 102 subpart B for making inquiries about records covered by the Privacy Act. Requesters should provide their name, address, and record sought in accordance with the procedures for making inquiries appearing in 37 CFR 102 subpart B.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

No exemptions claimed.

HISTORY:

None.

Dated: February 11, 2020.

Frederick W. Steckler,

Chief Administrative Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2020–03068 Filed 2–14–20; 8:45 am]

BILLING CODE 3510–16–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities Under OMB Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (''PRA''), this notice announces that the Information Collection Request (''ICR'') abstracted below has been forwarded to he Office of Management and Budget (''OMB'') for review and comment. The ICR describes the nature of the information collection and its expected costs and burden.

DATES: Comments must be submitted on or before March 19, 2020.

ADDRESSES: Comments regarding the burden estimate or any other aspect of the information collection, including

suggestions for reducing the burden, may be submitted directly to the Office of Information and Regulatory Affairs (''OIRA'') in OMB within 30 days of this notice's publication by either of the following methods. Please identify the comments by ''OMB Control No. 3038–0055.''

• *By email addressed to: OIRAsubmissions@omb.eop.gov* or

• *By mail addressed to:* The Office of Information and Regulatory Affairs, Office of Management and Budget, Attention Desk Officer for the Commodity Futures Trading Commission, 725 17th Street NW, Washington, DC 20503.

A copy of all comments submitted to OIRA should be sent to the Commodity Futures Trading Commission (''CFTC'' or ''Commission'') by either of the following methods. The copies should refer to ''OMB Control No. 3038–0055.''

• *By mail addressed to:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581;

• By Hand Delivery/Courier to the same address; or

• Through the Commission's website at *http://comments.cftc.gov.* Please follow the instructions for submitting comments through the website.

Please submit your comments to the Commission using only one method. A copy of the supporting statement for the collection of information discussed herein may be obtained by visiting *http://RegInfo.gov.*

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.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, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[1] 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 *http://www.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 ICR 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 the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Jacob Chachkin, Special Counsel, Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, (202) 418–5496, email: *jchachkin@cftc.gov,* and refer to OMB Control No. 3038–0055.

SUPPLEMENTARY INFORMATION:

Title: Privacy of Consumer Financial Information (OMB Control No. 3038–0055). This is a request for an extension of a currently approved information collection.

Abstract: Section 124 of the Commodity Futures Modernization Act of 2000[2] amended the Commodity Exchange Act (the ''Act'') and added a new Section 5g[3] to the Act to (i) add that futures commission merchants, commodity trading advisors, commodity pool operators, and introducing brokers that are subject to CFTC jurisdiction with respect to any financial activity shall be treated as a financial institution for purposes of Title V, Subtitle A of the Gramm-Leach-Bliley Act (''GLB Act''), (ii) treat the Commission as a Federal functional regulator for purposes of applying the provisions of the GLB Act, and (iii) direct the Commission to prescribe regulations under Title V of the GLB Act. The Commission adopted regulations for these entities under part 160 and later extended them to retail foreign exchange dealers, swap dealers, and major swap participants.[4] Part 160 requires those subject to the regulations, among other things, to provide privacy and opt out notices to customers and to adopt appropriate policies and procedures to safeguard customer records and information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. On December 11, 2019, the Commission published in the **Federal Register** notice of the proposed extension of this information collection and provided 60 days for public comment on the proposed extension, 84 FR 67724 (''60-Day Notice''). The Commission did not receive any relevant comments on the 60-Day Notice.

Burden Statement: The respondent burden for this collection is estimated to be as follows:

Estimated Number of Respondents: 2,789.

Estimated Average Burden Hours per Respondent: 3.0326.

Estimated Total Annual Burden Hours: 8,458.

Frequency of Collection: As applicable.

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: February 11, 2020.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2020–03056 Filed 2–14–20; 8:45 am]

BILLING CODE 6351–01–P

[1] 17 CFR 145.9.

[2] Section 124, Appendix E of Public Law 106–554, 114 Stat. 2763 (2000).

[3] 7 U.S.C. 7b–2.

[4] 17 CFR part 160. See Privacy of Customer Information, 66 FR 21235 (April 27, 2001); Regulation of Off-Exchange Retail Foreign Exchange Transactions and Intermediaries, 75 FR 55409 (Sept. 10, 2010); and Privacy of Consumer Financial Information; Conforming Amendments Under Dodd-Frank Act, 76 FR 43874 (July 22, 2011).

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 9:30 a.m., Thursday, February 20, 2020.

PLACE: CFTC Headquarters, Lobby-Level Hearing Room, Three Lafayette Centre, 1155 21st Street NW, Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commodity Futures Trading Commission (''Commission'' or ''CFTC'') will hold this meeting to consider the following matters:

• *Proposed Rule:* Amendments to the Real-Time Public Reporting Requirements (Part 43);

• *Proposed Rule:* Amendments to the Swap Data Recordkeeping and Reporting Requirements (Part 45); and

• *Reopening of Comment Period:* Certain Swap Data Repository and Data Reporting Requirements (Part 49 Verification).

The agenda for this meeting will be available to the public and posted on the Commission's website at *https://www.cftc.gov.* In the event that the time, date, or place of this meeting changes, 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: February 13, 2020.

Christopher Kirkpatrick,

Secretary of the Commission.

[FR Doc. 2020–03217 Filed 2–13–20; 4:15 pm]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Innovation Board; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Research and Engineering, Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Innovation Board will take place.

DATES: Open to the public, Thursday, March 5, 2020 from 2:00 p.m. to 4:00 p.m.

ADDRESSES: The meeting will be held at Capital Factory, 701 Brazos St., Austin, TX 78701.

FOR FURTHER INFORMATION CONTACT: Colleen Laughlin, 571–372–0933 (Voice), (Facsimile), *colleen.r.laughlin.civ@mail.mil* (Email). Mailing address is Defense Innovation Board, 9010 Defense Pentagon, Room 5E572, Washington, DC 20301–9010. Website: *https://innovation.defense.gov/.* The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.140 and 102–3.150.

Purpose of the Meeting: To obtain, review, and evaluate information related to the Board's mission in advising the Secretary of Defense and the Deputy Secretary of Defense independent advice and recommendations on innovative means to address future challenges in terms of integrated change to organizational structure and processes, business and functional concepts, and technology applications. The Board focuses on (a) technology and capabilities, (b) practices and operations, (c) people and culture, and (d) other research and analysis of topics raised by the Secretary of Defense, Deputy Secretary of Defense, or the Under Secretary of Defense for Research and Engineering.

Agenda: The meeting will begin on March 5, 2020 at 2:00 p.m. with opening remarks by Ms. Colleen Laughlin, the Designated Federal Officer (DFO), and Dr. Eric Schmidt, Board Chair. The Workforce, Behavior, and Culture Subcommittee will present on workforce issues, to include recommendations for a Chief Digital Engineering and Recruiting Management Officer. The Science and Technology Subcommittee will present on a Biotechnology and Data Strategy for the Joint Pathology Center to include presentations from external experts. The Science and Technology committee will also share progress updates from ongoing projects. Following all updates the board will deliberate and vote on pertinent recommendations. The Board will receive an update from the Department on the implementation status of its recommendations. The meeting will adjourn at 4:00 p.m.

Meeting Accessibility: Pursuant to Federal statutes and regulations (the FACA, the Sunshine Act, and 41 CFR 102–3.140 through 102–3.165) and the availability of space, the meeting is open to the public from 2:00 p.m. to 4:00 p.m. Seating is on a first-come basis. Members of the public wishing to attend the meeting or wanting to receive a link to the live stream webcast should register on the Board website, *http://innovation.defense.gov/meetings,* no later than February 27, 2020. Members of the media should RSVP to the Office of the Assistant to the Secretary of Defense (Public Affairs), at *osd.pentagon.pa.list.dop-atl@mail.mil.*

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact the DFO, see the **FOR FURTHER INFORMATION CONTACT** section for contact information, no later than February 27, 2020, so that appropriate arrangements can be made.

Written Statements: Written comments may be submitted to the DFO via email to mailbox address: *osd.innovation@mail.mil* in either Adobe Acrobat or Microsoft Word format. The DFO will compile all written submissions and provide them to Board members for consideration. Please note that because the Board operates under the provisions of the FACA, all submitted comments will be treated as public documents and will be made available for public inspection, including, but not limited to, being posted on the Board's website.

Oral Statements: Individuals wishing to make an oral statement to the Board at the public meeting may be permitted to speak for up to two minutes. Anyone wishing to speak to the Board should submit a request by email at *osd.innovation@mail.mil* no later than February 27, 2020 for planning. Requests for oral comments should include a copy or summary of planned remarks for archival purposes. Individuals may also be permitted to submit a comment request at the public meeting; however, depending on the number of individuals requesting to speak, the schedule may limit participation. Webcast attendees will be provided instructions with the live stream link if they wish to submit comments during the open meeting.

Dated: February 12, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–03113 Filed 2–14–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2019–ICCD–0153]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Formula Grant EASIE Electronic Application System for Indian Education

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before March 19, 2020.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2019–ICCD–0153. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments*

submitted by fax or email and those submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W–208D, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Kimberly Smith, 202–453–6469.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Formula Grant EASIE Electronic Application System for Indian Education.

OMB Control Number: 1810–0021.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 11,300.

Total Estimated Number of Annual Burden Hours: 9,590.

Abstract: The Indian Education Formula Grant (CFDA 84.060A) requires the annual submission of the application from the local educational agency and/or tribe. The amount of each applicant's award is determined by formula, based upon the reported number of American Indian/Alaska Native students identified in the application, the state per pupil expenditure, and the total appropriation available. Applicants provide the data required for funding electronically, and the Office of Indian Education (OIE) is able to apply electronic tools to facilitate the review and analysis leading to grant awards. The application has been named Formula Grant Electronic Application System for Indian Education (EASIE), and is located in the EDFacts System (ESS) website.

Dated: February 12, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2020–03117 Filed 2–14–20; 8:45 am]

BILLING CODE 4000–01–P

ELECTION ASSISTANCE COMMISSION

EAC 2020 Elections Disability, Accessibility, and Security Forum

AGENCY: U.S. Election Assistance Commission.

ACTION: Meeting notice; open to the public.

DATES: Thursday, February 20, 2020, 9:00 a.m.–3:00 p.m. (EDT).

ADDRESSES: Westin Georgetown, 2350 M St. NW, The Washington Room, Washington, DC 20037.

FOR FURTHER INFORMATION CONTACT: Patrick Leahy at (301) 960–1833.

SUPPLEMENTARY INFORMATION:

Agenda

The US Election Assistance Commission (EAC) is hosting an all-day forum to address growing concerns regarding accessibility and security in election administration. This forum will bring together state and local election officials, people with disabilities, disability advocates, and election security experts to discuss issues and potential actionable items. Agenda discussion topics will include: (1) The 2020 elections and voters with disabilities, (2) ballot-marking devices, (3) proven best practices in voting accessibility, (4) vote-by-mail, (5) electronic ballot delivery, and (6) emerging voting technology for people with disabilities. The EAC is committed to upholding the voting rights of people with disabilities established under the Help America Vote Act (HAVA) and Americans with Disabilities Act (ADA) amidst growing security needs. The full agenda will be posted in advance on the EAC website: *https://www.eac.gov.*

The Forum will be recorded and live streamed. The recording will be made available on the EAC website at a later date.

As space is limited, attendees are encouraged to register. Registration instructions and additional event information will be posted on the EAC event web page: *https://www.eac.gov/events/2020/02/20/2020-elections-disability-accessibility-and-security-forum.*

Nichelle S. Williams,

Director of Research, U.S. Election Assistance Commission.

[FR Doc. 2020–03053 Filed 2–14–20; 8:45 am]

BILLING CODE 6820–KF–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG20–80–000.

Applicants: Great Bay Solar II, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Great Bay Solar II, LLC.

Filed Date: 2/7/20.

Accession Number: 20200207–5140.

Comments Due: 5 p.m. ET 2/28/20.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER20–791–001.

Applicants: Midcontinent Independent System Operator, Inc., Otter Tail Power Company.

Description: Tariff Amendment: 2020–02–10_SA 3386 OTP-Tatanka Ridge Wind Sub FSA (J493) Hankinson-Wahpeton to be effective 3/15/2020.

Filed Date: 2/10/20.

Accession Number: 20200210–5063.

Comments Due: 5 p.m. ET 3/2/20.

Docket Numbers: ER20–965–000.

Applicants: California Independent System Operator Corporation.

Description: Tariff Cancellation: 2020–02–07 Notice of Cancellation of RCSA with LADWP to be effective 1/24/2020.

Filed Date: 2/7/20.

Accession Number: 20200207–5122.

Comments Due: 5 p.m. ET 2/28/20.

Docket Numbers: ER20–966–000.

Applicants: Montana-Dakota Utilities Co.

Description: Request for Limited Waiver, et al. of Montana-Dakota Utilities Co.

Filed Date: 2/7/20.

Accession Number: 20200207–5182.

Comments Due: 5 p.m. ET 2/28/20.

Docket Numbers: ER20–967–000.

Applicants: Great Bay Solar II, LLC.

Description: Baseline eTariff Filing: MBR Application and Tariff to be effective 3/15/2020.

Filed Date: 2/10/20.

Accession Number: 20200210–5042.

Comments Due: 5 p.m. ET 3/2/20.

Docket Numbers: ER20–968–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: BPA Metering Agreement—WEID to be effective 2/11/2020.

Filed Date: 2/10/20.

Accession Number: 20200210–5072.

Comments Due: 5 p.m. ET 3/2/20.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 10, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–03061 Filed 2–14–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC20–3–000]

Commission Information Collection Activities (FERC–574); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection FERC–574 (Gas Pipeline Certificates: Hinshaw Exemption) and submitting the information collection to the Office of Management and Budget (OMB) for review. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below.

DATES: Comments on the collection of information are due by March 19, 2020.

ADDRESSES: Comments filed with OMB, identified by the OMB Control No. 1902–0116, should be sent via email to the Office of Information and Regulatory Affairs: *oira_submission@omb.gov.* Attention: Federal Energy Regulatory Commission Desk Office.

A copy of the comments should also be sent to the Commission, in Docket No. IC20–3–000, by either of the following methods:

- *eFiling at Commission's Website: http://www.ferc.gov/docs-filing/efiling.asp.*
- *Mail:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663, and fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Title: FERC–574 (Gas Pipeline Certificates: Hinshaw Exemption).

OMB Control No.: 1902–0116.

Type of Request: Three-year extension of the FERC–574 with no changes to the current reporting requirements.

Abstract: On November 26, 2019 (84 FR 65148), the Commission published a Notice in the **Federal Register** in Docket No. IC20–3–000 requesting public comments. The Commission received no comments and is noting that in the related submittal to OMB. On December 19, 2019, OMB granted the Commission an emergency extension for FERC–574, from December 31, 2019 to March 31, 2020.

The Commission uses the information collected under the requirements of FERC–574 to implement the statutory provisions of Sections 1(c), 4, and 7 of the Natural Gas Act (NGA). Natural gas pipeline companies file applications with the Commission furnishing information in order to facilitate a determination of an applicant's qualification for an exemption under the provisions of the section 1(c). If the Commission grants an exemption, the natural gas pipeline company is not required to file certificate applications, rate schedules, or any other applications or forms prescribed by the Commission.

The exemption applies to companies engaged in the transportation, sale, or resale of natural gas in interstate commerce if: (a) They receive gas at or within the boundaries of the state from another person at or within the boundaries of that state; (b) such gas is ultimately consumed in such state; (c) the rates, service and facilities of such company are subject to regulation by a State Commission; and (d) that such State Commission is exercising that jurisdiction. 18 CFR part 152 specifies the data required to be filed by pipeline companies for an exemption.

Type of Respondents: Pipeline companies.

Estimate of Annual Burden: [1] The Commission estimates the annual public reporting burden and cost [2] for the information collection as:

[1] "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. See 5 CFR 1320 for additional information on the definition of information collection burden.

[2] Commission staff estimates that the industry's skill set and cost (for wages and benefits) for FERC–574 are approximately the same as the Commission's average cost. The FERC 2019 average salary plus benefits for one FERC full-time equivalent (FTE) is $167,091/year (or $80.00/hour).

FERC–574—GAS PIPELINE CERTIFICATES: HINSHAW EXEMPTION

Number of respondents (1)	Number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden hours & average cost ($) per response (4)	Total annual burden hours & total annual cost ($) (3) * (4) = (5)	Cost ($) per respondent (5) ÷ (1) = (6)
2	1	2	60 hours; $4,800	120 hours; $9,600	$4,800

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: February 11, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–03124 Filed 2–14–20; 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: RP20–505–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: § 4(d) Rate Filing: PAL Rate Adjustment Filing to be effective 3/8/2020.
Filed Date: 2/6/20.
Accession Number: 20200206–5061.
Comments Due: 5 p.m. ET 2/18/20.

Docket Numbers: RP20–506–000.
Applicants: Dauphin Island Gathering Partners.
Description: Storm Surcharge Adjustment Filing for 2020 of Dauphin Island Gathering Partners under RP20–506.
Filed Date: 2/7/20.
Accession Number: 20200207–5035.
Comments Due: 5 p.m. ET 2/19/20.

Docket Numbers: RP20–507–000.
Applicants: Enable Mississippi River Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Filing—Elementis Specialties RP18–923 & RP20–131 Settlement to be effective 1/1/2019.
Filed Date: 2/7/20.
Accession Number: 20200207–5119.
Comments Due: 5 p.m. ET 2/19/20.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 10, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–03060 Filed 2–14–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC19–25–000]

Commission Information Collection Activities (FERC–551); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–551 (Reporting of Flow Volume and Capacity by Interstate Natural Gas Pipelines).

DATES: Comments on the collection of information are due March 19, 2020.

ADDRESSES: Comments filed with OMB, identified by the OMB Control No. 1902–0243, should be sent via email to the Office of Information and Regulatory Affairs: *oira_submission@omb.gov.* Attention: Federal Energy Regulatory Commission Desk Officer:

A copy of the comments should also be sent to the Commission, in Docket No. IC19–25–000, by either of the following methods:

- *eFiling at Commission's Website: http://www.ferc.gov/docs-filing/efiling.asp.*
- *Mail/Hand Delivery/Courier:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for a text telephone (TTY).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663, and fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Title: FERC–551, Reporting of Flow Volume and Capacity by Interstate Natural Gas Pipelines.

OMB Control No.: 1902–0243.

Type of Request: Three-year extension of the FERC–551 information collection requirements with no changes to the current reporting requirements.

Abstract: The Commission is authorized to facilitate price transparency in markets for the sale or transportation of physical natural gas in interstate commerce, having due regard for the public interest, the integrity of

those markets, fair competition, and the protection of consumers. FERC–551 uses the information provided by pipelines as part of its overall implementation of the statutory provisions of section 23 of the Natural Gas Act, 16 U.S.C. 717t–2. More specifically, the Commission relies, in part, on section 23(a)(1) of the Natural Gas Act, for authority to collect this information and uses the pipelines' FERC–551 postings as part of fulfilling the transparency provisions of section 23(a)(1) of the Natural Gas Act. The data requirements for pipelines are in listed the Code of Federal Regulations (CFR) under 18 CFR 284.13, reporting requirements for interstate pipelines. The Commission has directed that the data requirements under FERC–551 are to be posted on interstate pipelines' websites and provided in downloadable file formats, in conformity with 18 CFR 284.12.

The posting requirements are based on the Commission's authority under section 23 of the NGA (as added by the Energy Policy Act of 2005), which provides, in relevant part, that the Commission may issue such rules as necessary and appropriate to provide for the dissemination of ''information about the availability and prices of natural gas at wholesale and in interstate commerce.'' [1] This provision enhances the Commission's authority to ensure confidence in the nation's natural gas markets. The Commission's market-oriented policies for the wholesale natural gas industry require that interested persons have broad confidence that reported market prices accurately reflect the interplay of legitimate market forces. Without confidence in the efficiency of price formation, the true value of transactions is very difficult to determine. Further, price transparency facilitates ensuring that jurisdictional prices are ''just and reasonable.'' [2]

The posting of FERC–551 information occurs on a daily basis. The data must be available for download for not less than 90 days from the date of posting and must be retained by the pipeline for three years.

The daily posting requirements for major non-interstate pipelines prescribed in the Commission's Order No. 720 are no longer required. The number of respondents used to develop the burden estimates do not include any major non-interstate pipelines.

Type of Respondents: Interstate Natural Gas Pipelines.

Estimate of Annual Burden [3]: The Commission estimates the total public reporting burden and cost for this information collection as follows:

FERC–551—REPORTING OF FLOW VOLUME AND CAPACITY BY INTERSTATE NATURAL GAS PIPELINES [4]

	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden & cost per response [5] (4)	Total annual burden hours & total annual cost (3) * (4) = (5)	Burden hour & cost per respondent ($) (5) ÷ (1)
FERC–551	172	365	62,780	0.5 hours; $25.59 ...	31,390 hrs.; $1,606,540.20.	182.5 hrs.; $9,340.35

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: February 11, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–03122 Filed 2–14–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3409–032]

Boyne USA, Inc.; Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent Minor License.

b. *Project No.:* 3409–032.

c. *Date Filed:* January 31, 2020.

[1] Section 23(a)(2) of the NGA, 15 U.S.C. 717t–2(a)(2) (2000 & Supp. V 2005).

[2] *See* sections 4 and 5 of the NGA, 15 U.S.C. 717c and 717d.

[3] Burden is defined as 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.

[4] The hourly figures in the 30-day notice differ from the wages used in the 60-day notice. The figures used here are the most current figures from the Bureau of Labor Statistics for the National Industry-Specific Occupational Employment and Wage Estimates.

[5] The hourly figure (wages plus benefits) is based on the average of the occupational categories for 2018 found on the Bureau of Labor Statistics website (*http://www.bls.gov/oes/current/naics2_22.htm* and *http://www.bls.gov/news.release/ecec.nr0.htm*):

—*Management (Occupation Code:* 11–0000): $66.67

—*Business (Occupation Code:* 13–0000): $41.98

—*Financial (Occupation Code:* 13–2051): $44.92

These various occupational categories' wage (and benefits) figures are averaged and weighted equally, giving an average of $51.19/hour. The resulting wage figure is rounded to $51.00/hour for use in calculating wage figures in the FERC–551 renewal.

d. *Applicant:* Boyne USA, Inc.

e. *Name of Project:* Boyne River Hydroelectric Project.

f. *Location:* On the Boyne River in Boyne Valley Township, Charlevoix County, Michigan.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)–825(r).

h. *Applicant Contact:* Randall Sutton, Boyne Mountain Resort Area Manager Boyne USA, Inc., P.O. Box 19, Boyne Falls, MI 49713; (231) 549–6076; *rsutton@boynemountain.com.*

i. *FERC Contact:* Patrick Ely at *patrick.ely@ferc.gov* or (202) 502–8570.

j. *Cooperating Agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See,* 94 FERC 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. *Deadline for filing additional study requests and requests for cooperating agency status:* March 31, 2020.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, 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–3409–032.

m. The application is not ready for environmental analysis at this time.

n. The Boyne River Hydroelectric Project (project) consists of a reservoir with a gross storage capacity of 356 acre-feet and a surface area of 68 acres at a pool elevation of 636.8 feet National Geodetic Vertical Datum 1988. The project includes: (a) An existing 610-foot-long by 30-foot-high (left) earth-fill dam embankment, a 180-foot-long by 18-foot-high (right) earth-fill dam embankment, a 75-foot-long concrete spillway; (b) a 132-foot-long by 50 to 72-foot-wide by 12-foot-deep concrete lined headrace channel; (c) a 74-foot-long steel penstock consisting of two 5-foot-diameter and one 7-foot-diameter sections; (d) a 20-foot-long by 8.3-foot-wide to 16-foot-wide by 4-foot-deep stilling basin; and (e) a 24-foot-long by 24-foot-wide concrete powerhouse with a single 250-kilowatt propeller turbine. The project also consists of a 2.5-mile-long, 12.5-kilovolt transmission line and appurtenant facilities. The project generates about 661 megawatt-hours annually. The applicant proposes to continue to operate the project in a run-of-river mode.

o. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website at *http://www.ferc.gov* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. *Procedural schedule and final amendments:* The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Issue Deficiency Letter (if necessary)—March 2020

Request Additional Information (if necessary)—March 2020

Issue Scoping Document 1 for comments—July 2020

Request Additional Information (if necessary)—September 2020

Issue Scoping Document 2 (if necessary)—October 2020

Issue Notice of Ready for Environmental Analysis—October 2020

Commission issues EA—April 2021

Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: February 11, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–03125 Filed 2–14–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Filing

	Docket Nos.
Balfour, Scott C.	ID–7646–004
Bennett, Robert R.	ID–7647–002
Blunden, Gregory W.	ID–7981–001
Muldoon, Daniel P.	ID–8749–001
Schwartz, David E.	ID–3396–002
Strickland, Valerie C.	ID–8254–001
Weatherford, William W.	ID–8850–000

Take notice that on February 10, 2020, Scott C. Balfour, Robert R. Bennett, Gregory W. Blunden, Daniel P. Muldoon, David E. Schwartz, Valerie C. Strickland, and William W. Weatherford, submitted for filing, applications for authority to hold interlocking positions, pursuant to section 305(b) of the Federal Power Act, 16 U.S.C. 825d(b) (2019) and section 45.8 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR part 45.8 (2019).

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the eLibrary link and is available for electronic review in the Commission's Public

Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on March 2, 2020.

Dated: February 10, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–03062 Filed 2–14–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2879–012]

Green Mountain Power Corporation; Notice of Application Tendered For Filing With the Commission and Establishing Procedural Schedule for Licensing and Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 2879–012.

c. *Date Filed:* January 30, 2020.

d. *Applicant:* Green Mountain Power Corporation (Green Mountain Power).

e. *Name of Project:* Bolton Falls Hydroelectric Project.

f. *Location:* The existing project is located on the Winooski River in Washington County, Vermont. The project does not affect federal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. John Greenan, P.E., Engineer, Green Mountain Power Corporation, 1252 Post Road, Rutland, Vermont 05701; phone: (802) 770–2195 or email at *John.Greenan@greenmountainpower.com.*

i. *FERC Contact:* Michael Tust, (202) 502–6522 or *michael.tust@ferc.gov.*

j. This application is not ready for environmental analysis at this time.

k. Project *Description:* The project consists of the following constructed facilities: (1) A 92-foot-high, 275-foot-wide timber crib dam with a 5-foot-high rubber dam atop the timber crib construction with a maximum crest elevation of 397 feet referenced to National Geodetic Vertical 1929 Datum and a 196-foot-long reinforced concrete spillway cap at a crest elevation of 392 feet; (2) a 59-acre impoundment with a total storage capacity of 300 acre-feet at a normal operating elevation of 397 feet; (3) a forebay with two concrete intakes, each with a 3-inch-spaced trashrack; (4) two 10-foot diameter, 120-foot-long steel penstocks encased in concrete, extending from each intake through the dam to the generating units; (5) a 73-foot-long, 57-foot-wide powerhouse containing two horizontal, 3,750-kilowatt Kaplan turbines with a total installed capacity of 7,500 kilowatts; (6) a 36-inch diameter steel bypass pipe with an invert elevation of 383 feet that discharges near the left side of the spillway base; (7) an approximately 130-foot long, 5-kilovolt underground transmission line connecting to an adjacent switchyard; (8) a 600-foot-long, 34.5-kilovolt overhead transmission line connecting to a second switchyard; and (9) appurtenant facilities. Green Mountain Power also maintains day-use recreation facilities at the project, including a picnic area, parking lot, trails, fishing access, and a canoe launch and portage trail.

Green Mountain Power proposes to operate in automated run-of-river mode as it does under its current practice but instead of providing a 300-cfs minimum flow into the bypassed reach via spill over the dam or through the powerhouse, Green Mountain Power proposes to provide a seasonal aesthetic spill flow of 75 cfs or inflow, whichever is less, into the bypassed reach during daylight hours from April 1 through December 15. Green Mountain Power would only provide leakage flows from the dam into the bypassed reach during nighttime hours from April 1 through December 15 as well as during day and nighttime hours from December 16 through March 31. Under normal flow conditions during periods when aesthetic spillage is required, Green Mountain proposes to maintain the impoundment at an elevation of 397.25 feet. During periods when aesthetic spillage over the dam is not required, Green Mountain Power proposes to maintain the reservoir at an elevation of 397 feet as it does under its existing operation. In addition to operating and maintaining its existing recreation facilities, Green Mountain Power proposes the following improvements to its recreation facilities: (1) Relocate the existing parking area out of the floodplain; (2) place barriers and signage to redirect foot traffic away from areas with state-designated rare creeping lovegrass at the day-use area; (3) add two picnic tables and an information kiosk to the day-use area; (4) improve signage at the portage landing and along the portage trail for boaters; (5) construct an improved portage landing; and (6) clear brush along the portage trail.

Green Mountain Power is proposing to remove approximately 9.2 acres of lands and water from the current project boundary because these areas do not contain any project recreation facilities and are not necessary for project operation and maintenance. These areas include 4.2 acres of land south of the existing portage trail and northwest of the VELCO transmission line, 2.9 acres of land south of Power Plant Road, and 2.1 acres of the Winooski River and shoreline downstream of the dam located outside of the project bypassed reach and tailrace. In addition, Green Mountain Power is proposing to add approximately 7.6 acres of land to the project boundary. These areas include: (1) Approximately 1.4 acres of land along a secondary access road located to the south of the portage trail take-out; (2) approximately 4.1 acres of land along the middle section of the portage trail to fully enclose the portage trail; and (3) approximately 2.1 acres of lands along the primary project access road to provide vehicular and pedestrian access to the project for operation and maintenance purposes as well as access to the project's day-use recreation area.

l. *Locations of the Application:* A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website at *http://www.ferc.gov* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY).

m. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. *Procedural Schedule:* The application will be processed according to the following preliminary Hydro Licensing Schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Notice of Acceptance/Notice of Ready for Environmental Analysis	March 2020.
Filing of recommendations, preliminary terms and conditions, and fishway prescriptions	May 2020.
Commission issues Draft Environmental Assessment (EA)	November 2020.
Comments on Draft EA	December 2020.
Modified terms and conditions	February 2021.
Commission issues Final EA	May 2021.

o. Final amendments to the application must be filed with the Commission no later than thirty (30) days from the issuance date of the notice of ready for environmental analysis.

Dated: February 10, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–03064 Filed 2–14–20; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10005–08–Region 8]

Public Water System Supervision Program Revision for the State of South Dakota

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Public notice is hereby given that the state of South Dakota has revised its Public Water System Supervision (PWSS) Program by adopting federal regulations for the Revised Total Coliform Rule (RTCR) that correspond to the National Primary Drinking Water Regulations (NPDWR). The EPA has reviewed South Dakota's regulations and determined they are no less stringent than the federal regulations. The EPA is proposing to approve South Dakota's primacy revision for the RTCR.

This approval action does not extend to public water systems in Indian country. Please see **SUPPLEMENTARY INFORMATION**, section B.

DATES: Any member of the public is invited to request a public hearing on this determination by March 19, 2020. Please see **SUPPLEMENTARY INFORMATION**, section C, for details. Should no timely and appropriate request for a hearing be received, and the Regional Administrator (RA) does not elect to hold a hearing on his/her own motion, this determination shall become applicable March 19, 2020. If a public hearing is requested and granted, then this determination shall not become applicable until such time following the hearing as the RA issues an order affirming or rescinding this action.

ADDRESSES: Requests for a public hearing should be addressed to: Robert Clement, Drinking Water B Section, EPA Region 8, 1595 Wynkoop Street, Denver, CO 80202–1129.

All documents relating to this determination are available for inspection at: EPA Region 8, Drinking Water Section (5th floor), 1595 Wynkoop Street, Denver, Colorado.

FOR FURTHER INFORMATION CONTACT: Robert Clement, Drinking Water B Section, EPA Region 8, 1595 Wynkoop Street, Denver, CO 80202–1129, phone 303–312–6653.

SUPPLEMENTARY INFORMATION: In accordance with the provisions of section 1413 of the Safe Drinking Water Act (SDWA), 42 U.S.C. 300g–2, and 40 CFR 142.13, public notice is hereby given that the state of South Dakota has revised its PWSS program by adopting federal regulations for the RTCR that correspond to the NPDWR in 40 CFR parts 141 and 142. The EPA has reviewed South Dakota's regulations and determined they are no less stringent than the federal regulations. The EPA is proposing to approve South Dakota's primacy revision for the RTCR.

This approval action does not extend to public water systems in Indian country as defined in 18 U.S.C. 1151. Please see **SUPPLEMENTARY INFORMATION**, section B.

A. Why are revisions to State programs necessary?

States with primary PWSS enforcement authority must comply with the requirements of 40 CFR part 142 to maintain primacy. They must adopt regulations that are at least as stringent as the NPDWRs at 40 CFR parts 141 and 142, as well as adopt all new and revised NPDWRs in order to retain primacy (40 CFR 142.12(a)).

B. How does this action affect Indian country (18 U.S.C. 1151) in South Dakota?

The EPA's approval of South Dakota's revised PWSS program does not extend to Indian country as defined in 18 U.S.C. 1151. Indian country in South Dakota generally includes (1) lands within the exterior boundaries of the following Indian reservations located within South Dakota, in part or in full: The Cheyenne River Reservation, the Crow Creek Reservation, the Flandreau Indian Reservation, the Lower Brule Reservation, the Pine Ridge Reservation, the Rosebud Indian Reservation, the Standing Rock Reservation, and the Yankton Reservation (subject to federal court decisions removing lands from Indian country status within the Yankton Reservation); (2) any land held in trust by the United States for an Indian tribe; and (3) any other areas which are ''Indian country'' within the meaning of 18 U.S.C. 1151. The EPA or eligible Indian tribes, as appropriate, will retain PWSS program responsibilities over public water systems in Indian country.

C. Requesting a Hearing

Any member of the public may request a hearing on this determination within thirty (30) days of this notice. All requests shall include the following information: Name, address, and telephone number of the individual, organization, or other entity requesting a hearing; a brief statement of interest and information to be submitted at the hearing; and a signature of the interested individual or responsible official, if made on behalf of an organization or other entity. Frivolous or insubstantial requests for a hearing may be denied by the RA.

Notice of any hearing shall be given not less than fifteen (15) days prior to the time scheduled for the hearing and will be made by the RA in the **Federal Register** and in a newspaper of general circulation in the state. A notice will also be sent to both the person(s) requesting the hearing and the state. The hearing notice will include a statement of purpose of the hearing, information regarding time and location for the hearing, and the address and telephone number where interested persons may obtain further information. The RA will issue an order affirming or rescinding the determination upon review of the hearing record.

Please bring this notice to the attention of any persons known by you to have an interest in this determination.

Dated: December 19, 2019.

Gregory E. Sopkin,

Regional Administrator, Region 8.

[FR Doc. 2020–03155 Filed 2–14–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2019–0075; FRL–9992–85]

Certain New Chemicals; Receipt and Status Information for November 2019

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is required under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to make information publicly available and to publish information in the **Federal Register** pertaining to submissions under TSCA Section 5, including notice of receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN) or Microbial Commercial Activity Notice (MCAN), including an amended notice or test information; an exemption application (Biotech exemption); an application for a test marketing exemption (TME), both pending and/or concluded; a notice of commencement (NOC) of manufacture (including import) for new chemical substances; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review. This document covers the period from 11/01/2019 to 11/30/2019.

DATES: Comments identified by the specific case number provided in this document must be received on or before March 19, 2020.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2019–0075, and the specific case number for the chemical substance related to your comment, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Jim Rahai, Information Management Division (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–8593; email address: *rahai.jim@epa.gov.*

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

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

This document provides the receipt and status reports for the period from 11/01/2019 to 11/30/2019. The Agency is providing notice of receipt of PMNs, SNUNs and MCANs (including amended notices and test information); an exemption application under 40 CFR part 725 (Biotech exemption); TMEs, both pending and/or concluded; NOCs to manufacture a new chemical substance; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review.

EPA is also providing information on its website about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its website at: *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices.* This information is updated on a weekly basis.

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

Under the TSCA, 15 U.S.C. 2601 *et seq.,* a chemical substance may be either an ''existing'' chemical substance or a ''new'' chemical substance. Any chemical substance that is not on EPA's TSCA Inventory of Chemical Substances (TSCA Inventory) is classified as a ''new chemical substance,'' while a chemical substance that is listed on the TSCA Inventory is classified as an ''existing chemical substance.'' (See TSCA section 3(11).) For more information about the TSCA Inventory go to: *https://www.epa.gov/tsca-inventory.*

Any person who intends to manufacture (including import) a new chemical substance for a non-exempt commercial purpose, or to manufacture or process a chemical substance in a non-exempt manner for a use that EPA has determined is a significant new use, is required by TSCA section 5 to provide EPA with a PMN, MCAN or SNUN, as appropriate, before initiating the activity. EPA will review the notice, make a risk determination on the chemical substance or significant new use, and take appropriate action as described in TSCA section 5(a)(3).

TSCA section 5(h)(1) authorizes EPA to allow persons, upon application and under appropriate restrictions, to manufacture or process a new chemical substance, or a chemical substance subject to a significant new use rule (SNUR) issued under TSCA section 5(a)(2), for ''test marketing'' purposes, upon a showing that the manufacture, processing, distribution in commerce, use, and disposal of the chemical will not present an unreasonable risk of injury to health or the environment. This is referred to as a test marketing exemption, or TME. For more information about the requirements applicable to a new chemical go to: *http://www.epa.gov/oppt/newchems.*

Under TSCA sections 5 and 8 and EPA regulations, EPA is required to publish in the **Federal Register** certain information, including notice of receipt of a PMN/SNUN/MCAN (including amended notices and test information); an exemption application under 40 CFR part 725 (biotech exemption); an application for a TME, both pending and concluded; NOCs to manufacture a new chemical substance; and a periodic status report on the new chemical substances that are currently under EPA review or have recently concluded review.

C. Does this action apply to me?

This action provides information that is directed to the public in general.

D. Does this action have any incremental economic impacts or paperwork burdens?

No.

E. What should I consider as I prepare my comments for EPA?

1. *Submitting confidential business information (CBI).* Do not submit this information to EPA through

regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. Status Reports

In the past, EPA has published individual notices reflecting the status of TSCA section 5 filings received, pending or concluded. In 1995, the Agency modified its approach and streamlined the information published in the **Federal Register** after providing notice of such changes to the public and an opportunity to comment (See the **Federal Register** of May 12, 1995, (60 FR 25798) (FRL–4942–7). Since the passage of the Lautenberg amendments to TSCA in 2016, public interest in information on the status of section 5 cases under EPA review and, in particular, the final determination of such cases, has increased. In an effort to be responsive to the regulated community, the users of this information, and the general public, to comply with the requirements of TSCA, to conserve EPA resources and to streamline the process and make it more timely, EPA is providing information on its website about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its website at: *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices.* This information is updated on a weekly basis.

III. Receipt Reports

For the PMN/SNUN/MCANs that have passed an initial screening by EPA during this period, Table I provides the following information (to the extent that such information is not subject to a CBI claim) on the notices screened by EPA during this period: The EPA case number assigned to the notice that indicates whether the submission is an initial submission, or an amendment, a notation of which version was received, the date the notice was received by EPA, the submitting manufacturer (*i.e.,* domestic producer or importer), the potential uses identified by the manufacturer in the notice, and the chemical substance identity.

As used in each of the tables in this unit, (S) indicates that the information in the table is the specific information provided by the submitter, and (G) indicates that this information in the table is generic information because the specific information provided by the submitter was claimed as CBI. Submissions which are initial submissions will not have a letter following the case number. Submissions which are amendments to previous submissions will have a case number followed by the letter ''A'' (*e.g.,* P–18–1234A). The version column designates submissions in sequence as ''1'', ''2'', ''3'', etc. Note that in some cases, an initial submission is not numbered as version 1; this is because earlier version(s) were rejected as incomplete or invalid submissions. Note also that future versions of the following tables may adjust slightly as the Agency works to automate population of the data in the tables.

TABLE I—PMN/SNUN/MCANS APPROVED * FROM 11/01/2019 TO 11/30/2019

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
J–19–0024A	2	9/10/2019	CBI	(G) Ethanol production	(G) Biofuel producting Saccharomyces cerevisiae modified, genetically stable.
J–19–0025A	2	9/10/2019	CBI	(G) Ethanol production	(G) Biofuel producting Saccharomyces cerevisiae modified, genetically stable.
J–19–0026A	2	11/13/2019	CBI	(G) Production of biofuel	(G) Biofuel-producing modified microorganism(s), with chromosomally-borne modifications.
J–19–0026A	3	11/15/2019	CBI	(G) Production of biofuel	(G) Biofuel-producing modified microorganism(s), with chromosomally-borne modifications.
J–19–0027A	2	11/13/2019	CBI	(G) Production of biofuel	(G) Biofuel-producing modified microorganism(s), with chromosomally-borne modifications.
J–19–0027A	3	11/15/2019	CBI	(G) Production of biofuel	(G) Biofuel-producing modified microorganism(s), with chromosomally-borne modifications.
P–16–0486A	4	11/1/2019	CBI	(G) Site-limited intermediate in the production of a refrigerant precursor.	(G) Polychloropropane.
P–17–0007A	6	11/15/2019	CBI	(S) Intermediate	(G) dialkyl 7,10-dioxa, dithiahexadeca diene.
P–17–0260A	3	11/21/2019	Shin Etsu Silicones of America.	(G) Resin modifier	(G) Alkoxy silane modified butadiene-styrene copolymer.
P–18–0019A	3	10/29/2019	Cabot Corporation.	(S) Dispersive pigment	(G) Substituted Benzene, 4-[2-[2-hydroxy-3-[[(3-nitrophenyl)amino]carbonyl]-1-naphthalenyl]diazenyl]-, sodium salt (1:1).
P–18–0029A	2	10/30/2019	CBI	(G) Industrial use in Oilfield.	(G) Fatty acids and fatty acid unsatd., reaction products with ethyleneamines and maleic anhydride.
P–18–0031A	6	11/20/2019	CBI	(G) Ingredient for industrial coating.	(G) Substituted dicarboxylic acid, polymer with various alkanediols.

TABLE I—PMN/SNUN/MCANS APPROVED * FROM 11/01/2019 TO 11/30/2019—Continued

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
P–18–0160A	4	11/11/2019	CBI	(G) Coating component	(G) Heteropolycyclic, halo substituted alkyl substituted- diaromatic amino substituted carbomonocycle, halo substituted alkyl substituted heteropolycyclic, tetraaromatic metalloid salt (1:1).
P–18–0165A	6	11/1/2019	Cabot Corporation.	(S) Chemical intermediate	(G) 2,5-Furandione, polymer with ethenylbenzene, 4-hydroxy-substituted butyl amide, sodium salts.
P–18–0166A	6	11/1/2019	Cabot Corporation.	(S) Chemical Intermediate	(G) 2,5-Furandione, polymer with ethenylbenzene, 4-hydroxy- substituted butyl [3-[2-[1-[[(2-methoxyphenyl)amino]carbonyl]-2-oxopropyl]diazenyl]phenyl]substituted, sodium salts.
P–18–0167A	4	11/6/2019	Cabot Corporation.	(S) Chemical intermediate	(G) Butanamide, 2-[2-[(substitutued phenyl)diazenyl]-N-(2-methoxyphenyl)-3-oxo-.
P–18–0190A	5	11/6/2019	Cabot Corporation.	(S) Pigment Dispersing Aid.	(G) 2,5-Furandione, polymer with ethenylbenzene, 4-hydroxy-substituted butyl amide, polymers with epichlorohydrin and trimethylolpropane, sodium salts.
P–18–0191A	5	11/6/2019	Cabot Corporation.	(S) Pigment Dispersing Aid.	(G) 2,5-Furandione, polymer with ethenylbenzene, 4-hydroxy-substitutedbutyl [3-[2-[1-[[(substitutedphenyl)amino]carbonyl]-2-oxopropyl]diazenyl]phenyl]methyl amide, polymers with epichlorohydrin and trimthylolpropane, sodium salts.
P–18–0213A	3	11/8/2019	CBI	(S) polyester or polyamide modifer incorporated into backbone of polymer.	(S) 1,3-Benzenedicarboxylic acid, 5-sulfo-, calcium salt (2:1).
P–18–0214A	4	11/21/2019	CBI	(G) Curing agent	(G) Polycyclic substituted alkane, polymer with cyclicalkylamine, epoxide, and polycyclic epoxide ether, reaction products with dialkylamine substituted alkyl amine.
P–18–0215A	4	11/21/2019	CBI	(G) Curing agent	(G) Polycyclic alkane, polymer with monocyclic amine, polycyclic epoxide ether, reaction products with dialkylamine alkyl amine.
P–18–0216A	4	11/21/2019	CBI	(G) Curing agent	(G) Polycyclic substituted alkane, polymer with epoxide, reaction products with cyclicalkylamine and dialkylamine substituted alkyl amine.
P–18–0236A	3	11/14/2019	The Sherwin Williams Company.	(G) Paint additive	(G) Metal, alkenoic acid-alkyl alkenoate-alkyl substituted alkenoate polymer carbopolycycle complexes.
P–18–0274A	7	11/5/2019	CBI	(S) Chemical intermediate and (G) Additive.	(G) Heterocycle fluoroalkyl sulfonyl.
P–18–0275A	6	11/5/2019	CBI	(G) Polymer additive	(G) Methanone phenylene fluoroalkyl sulfonyl heterocycle.
P–18–0363A	3	10/31/2019	CBI	(G) Adhesive	(G) Phenol, polymer with formaldehyde, substituted phenol, sodium salts.
P–18–0367	2	11/11/2019	Afcona Chemicals USA Inc.	(S) Acid-modified polyether used as a wetting and dispersing additive for pigments in industrial paints and coatings.	(M) (G) Acid-modified polyether.
P–18–0376A	2	11/5/2019	Sumitomo Chemical Advanced Technologies LLC.	(S) Substance used to improve physical properties in rubber products.	(G) Thiosulfuric acid, aminoalkyl ester.
P–18–0387A	4	11/11/2019	CBI	(G) Plastic Additive	(G) Alkanal, reaction products with alkanediyl bis[alkyl-tris(alkyl-heterocycle)-1,3,5-triazine-2,4,6-triamine and hydrogen peroxide.
P–18–0388A	4	11/11/2019	CBI	(G) Plastic additive	(G) 1,3,5-triazine-2,4,6-triamine, alkanediyl bis[alkyl-tris(alkyl-heterocycle)-, allyl derivs., oxidized, hydrogenated.
P–18–0399A	7	11/18/2019	CBI	(G) Open, non-dispersive use additive for industrial use only.	(G) Rosin adduct ester, polymer with polyols, compd. with ethanolamine.
P–18–0400A	7	11/18/2019	CBI	(G) Open, non-dispersive use, additive for textile industry.	(G) Rosin adduct ester, polymer with polyols, potassium salt.

TABLE I—PMN/SNUN/MCANS APPROVED * FROM 11/01/2019 TO 11/30/2019—Continued

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
P–19–0064A	5	10/30/2019	The Sherwin Williams Company.	(G) Polymeric film former for coatings.	(G) 4,4′-methylenebis[2,6-dimethyl phenol] polymer with 2-(chloromethyl)oxirane, 1,4-benzyl diol, 2-methyl-2-propenoic acid, butyl 2-methyl 2-propenoate, ethyl 2-methyl 2-propenoate, and ethyl 2-propenoate, reaction products with 2-(dimethylamino) ethanol.
P–19–0077A	8	11/12/2019	CBI	(G) Agricultural	(G) alkenylamide.
P–19–0143A	4	10/29/2019	Aditya Birla Chemicals (USA), LLC.	(S) A crosslinking agent for use in epoxy resin for water-based coating for a variety of substrates and civil applications in commercial and consumer usages.	(G) Aldehyde, polymer with mixed alkanepolyamines, 2,2′-[1,4-alkanediylbis(oxyalkylene)] bis[oxirane], 2-(alkoxyalkyloxirane, 4,4′-(1-alkylidene)bis[phenol], 2,2′-[(1-alkylidene)bis(4,1-alkyleneoxyalkylene)]bis[oxirane] and 2-(aryloxyalkyl)oxirane, acetate (salt).
P–19–0144A	4	10/29/2019	Aditya Birla Chemicals (USA), LLC.	(S) A crosslinking agent in epoxy based self-leveling floor coatings.	(G) Alkanedioic Acid, compds. With substituted arylalkylamine- arylalcohol disubstituted alkane-the diglycidyl ether of a arylalcohol disubstituted alkane -epichlorohydrin-aldehyde-2,2′-[(1-alkylidene)bis[4,1-aryleneoxy(alkyl-2,1-alkanediyl)oxyalkylene]]bis[oxirane]-alkanepolyamine polymer-1-[[2-[(2-aminoalkyl)amino]alkyl]amino]-3-aryloxy-2-alcohol reaction products.
P–19–0145A	5	11/7/2019	ARC Products, Inc.	(S) Oil Field Drilling Fluid Additive.	(G) Polyazaalkane with oxirane and methyloxirane, haloalkane.
P–19–0145A	6	11/14/2019	ARC Products, Inc.	(S) Oil Field Drilling Fluid Additive.	(G) Polyazaalkane with oxirane and methyloxirane, haloalkane.
P–19–0153A	4	11/6/2019	Wego Chemical Group.	(S) Raw material in Flame Retardant product.	(G) Dibromoalkyl ether Tetrabromobisphenol A.
P–19–0155A	4	10/30/2019	Huntsman International, LLC.	(S) Adjuvant for agrochemical formulations.	(S) Amides, from C8–18 and C18-unsatd. glycerides and diethylenetriamine, ethoxylated.
P–19–0156A	4	10/30/2019	Huntsman International, LLC.	(S) Adjuvant for agrochemical formulations.	(S) Amides, from diethylenetriamine and palm kernel-oil, ethoxylated.
P–19–0157A	4	10/30/2019	Huntsman International, LLC.	(S) Adjuvant in agrochemical formulations.	(S) Amides, from coconut oil and diethylenetriamine, ethoxylated.
P–19–0158A	5	10/29/2019	Ashland, Inc.	(G) Adhesive	(G) Alkenoic acid polymer with 2-ethyl-2-(hdroxymethyl)-1,3-alkyldiol, 1,1′-methylenebis(4-isocyantocarbomonocycle) and 3-methyl-1,5-aklydiol.
P–19–0165A	3	11/11/2019	ARBORIS, LLC.	(G) Plasticizer in rubber and Coating in minerals.	(G) Tall oil pitch, fraction, sterol-low.
P–19–0167A	3	10/31/2019	Santolubes Manufacturing, LLC.	(S) Synthetic engine, gear and lubricating oils and greases.	(S) Poly(oxy-1,4-butanediyl), alpha-hydro-omega-hydroxy-, hexanoate.
P–19–0167A	4	11/18/2019	Santolubes Manufacturing, LLC.	(S) Synthetic engine, gear and lubricating oils and greases.	(S) Poly(oxy-1,4-butanediyl), alpha-hydro-omega-hydroxy-, hexanoate.
P–19–0168A	4	11/1/2019	CBI	(G) Well performance tracer.	(G) Halogenated alkylbenzoic acid.
P–19–0169A	4	11/1/2019	CBI	(G) Well performance monitor.	(G) Halogenated alkylbenzoic acid.
P–19–0180A	5	11/1/2019	CBI	(G) Well performance monitor.	(G) Halogenated sodium benzoate.
P–19–0181A	5	11/1/2019	CBI	(G) Well performance monitor.	(G) Halogenated sodium benzoate.
P–19–0182A	5	11/1/2019	CBI	(G) Well performance monitor.	(G) Halogenated sodium benzoate.
P–20–0001A	3	10/29/2019	Santolubes Manufacturing, LLC.	(S) Synthetic engine, gear & lubricating oils &; greases.	(S) Poly(oxy-1,4-butanediyl), alpha-hydro-w-hydroxy-, nonanoate.
P–20–0001A	4	10/31/2019	Santolubes Manufacturing, LLC.	(S) Synthetic engine, gear & lubricating oils &; greases.	(S) Poly(oxy-1,4-butanediyl), alpha-hydro-omega-hydroxy-, nonanoate.

TABLE I—PMN/SNUN/MCANS APPROVED * FROM 11/01/2019 TO 11/30/2019—Continued

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
P–20–0002A	2	10/29/2019	Santolubes Manufacturing, LLC.	(S) Synthetic engine, gear & lubricating oils & greases.	(S) Fatty Acids, C18-unsatd., dimers, hydrogenated, polymers with alpha-hydro-w-hydroxypoly(oxy-1,4-butanediyl) and nonanoic acid.
P–20–0002A	4	10/29/2019	Santolubes Manufacturing, LLC.	(S) Synthetic engine, gear & lubricating oils & greases.	(S) Fatty Acids, C18-unsatd., dimers, hydrogenated, polymers with alpha-hydro-omega-hydroxypoly(oxy-1,4-butanediyl) and nonanoic acid.
P–20–0002A	5	10/31/2019	Santolubes Manufacturing, LLC.	(S) Synthetic engine, gear & lubricating oils & greases.	(S) Fatty Acids, C18-unsatd., dimers, hydrogenated, polymers with alpha-hydro-omega-hydroxypoly(oxy-1,4-butanediyl) and nonanoic acid.
P–20–0004A	2	10/29/2019	Santolubes Manufacturing, LLC.	(S) Synthetic engine, gear & lubricating oils & greases.	(S) Fatty Acids, C18-unsatd., dimers, hydrogenated, polymers with hexanoic acid and alpha-hydro-omega-hydroxypoly(oxy-1,4-butanediyl).
P–20–0004A	3	10/29/2019	Santolubes Manufacturing, LLC.	(S) Synthetic engine, gear & lubricating oils & greases.	(S) Fatty Acids, C18-unsatd., dimers, hydrogenated, polymers with hexanoic acid and alpha-hydro-w-hydroxypoly(oxy-1,4-butanediyl).
P–20–0004A	4	10/30/2019	Santolubes Manufacturing, LLC.	(S) Synthetic engine, gear & lubricating oils & greases.	(S) Fatty Acids, C18-unsatd., dimers, hydrogenated, polymers with hexanoic acid and alpha-hydro-omega-hydroxypoly(oxy-1,4-butanediyl).
P–20–0004A	5	10/30/2019	Santolubes Manufacturing, LLC.	(S) Synthetic engine, gear & lubricating oils & greases.	(S) Fatty Acids, C18-unsatd., dimers, hydrogenated, polymers with hexanoic acid and alpha-hydro-omega-hydroxypoly(oxy-1,4-butanediyl).
P–20–0005A	3	11/11/2019	RMC Advanced Technologies, Inc..	(G) Additive for plastics and resins.	(G) modified graphene.
P–20–0023	1	11/18/2019	CBI	(G) The notified substance will be used as a fragrance ingredient. It will be blended (mixed) with other fragrance ingredients to make fragrance oils. The fragrance oils containing the notified substance will then be incorporated into soaps, detergents, cleaners, air fresheners, candles and other similar commercial and consumer products.	(G) heteropolycycle, 2,6-dimethyl-3a-(1-methylethyl)-.
P–20–0025	1	11/19/2019	Biosynthetic Technologies.	(S) Motor oil lubricant, formulation #1 and formulation #2.	(S) Octadecanoic acid, 12-(acetoxy)-, 2-ethylhexyl ester.
SN–18–0002A ...	4	11/4/2019	CBI	(G) Flame retardant for textile.	(G) Phosphoramidic acid, carbomonocyclic-, diphenylester (accession number 261553).

* The term 'Approved' indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission prior to the start of the 90-day review period, and in no way reflects the final status of a complete submission review.

In Table II of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the NOCs that have passed an initial screening by EPA during this period: The EPA case number assigned to the NOC including whether the submission was an initial or amended submission, the date the NOC was received by EPA, the date of commencement provided by the submitter in the NOC, a notation of the type of amendment (*e.g.,* amendment to generic name, specific name, technical contact information, etc.) and chemical substance identity.

TABLE II—NOCS APPROVED * FROM 11/01/2019 TO 11/30/2019

Case No.	Received date	Commencement date	If amendment, type of amendment	Chemical substance
J–19–0017	11/14/2019	10/29/2019	N	(G) Genetically modified microorganism.
P–17–0007A	11/15/2019	9/20/2018	Y ..... CBI Substantiation provided	(G) Dialkyl 7,10-dioxa, dithiahexadeca diene.
P–18–0172	11/7/2019	11/6/2019	N	(G) Calcium carbonate carboxylate.
P–18–0276	11/5/2019	10/7/2019	N	(S) Benzenesulfonamide, N-[2-[[(phenylamino)carbonyl]amino]phenyl]-.

TABLE II—NOCS APPROVED * FROM 11/01/2019 TO 11/30/2019—Continued

Case No.	Received date	Commencement date	If amendment, type of amendment	Chemical substance
P–18–0312	11/6/2019	10/23/2019	N	(G) Formaldehyde, polymer with 2-phenoxyalkanol and alpha.-phenyl-.omega. hydroxypoly(oxy-1,2-alkylnediyl), dihydrogen phosphate 2-phenoxyalkyl hydrogen phosphate, alkaline salt.
P–18–0321	11/6/2019	10/23/2019	N	(G) Polyalkylene glycol.
P–19–0086	11/15/2019	11/15/2019	N	(S) Benzeneacetic acid, 2,3-difluoro-, sodium salt (1:1).
P–19–0087	11/15/2019	11/15/2019	N	(S) Benzeneacetic acid, 2-fluoro-, sodium salt (1:1).
P–19–0089	11/15/2019	11/15/2019	N	(S) Benzenepropanoic acid, 3-fluoro-, sodium salt (1:1).
P–19–0090	11/15/2019	11/15/2019	N	(S) Benzoic acid, 5-fluoro-2-methyl-, sodium salt (1:1).
P–19–0091	11/18/2019	11/18/2019	N	(S) Benzeneacetic acid, 2,3-difluoro-.
P–19–0092	11/18/2019	11/18/2019	N	(S) Benzenepropanoic acid, 3-fluoro-.
P–19–0096	11/21/2019	11/4/2019	N	(S) 2(3H)-Benzofuranone, 5,7-bis(1,1-dimethylethyl)-3-[3,5-dimethyl-4-[[2,4,8,10-tetrakis(1,1-dimethylethyl)-12-methyl- 12H-dibenzo[d,g][1,3,2]dioxaphosphocin-6-yl]oxy]phenyl]-.
P–19–0097	11/18/2019	11/18/2019	N	(S) Benzoic acid, 5-fluoro-2-methyl-, ethyl ester.
P–19–0100	11/18/2019	11/18/2019	N	(S) Benzoic acid, 4-fluoro-2-methyl-, ethyl ester.
P–19–0101	11/18/2019	11/18/2019	N	(S) Benzoic acid, 4-chloro-2-methyl-, ethyl ester.
P–19–0102	11/18/2019	11/18/2019	N	(S) Benzoic acid, 5-chloro-2-methyl-, ethyl ester.
P–19–0105	11/18/2019	11/18/2019	N	(S) Benzoic acid, 2-chloro-5-fluoro-, ethyl ester.
P–19–0106	11/18/2019	11/18/2019	N	(S) Benzoic acid, 2-chloro-5-methyl-, ethyl ester.
P–19–0107	11/18/2019	11/18/2019	N	(S) Benzoic acid, 3-fluoro-4-methyl-, ethyl ester.
P–19–0110	11/18/2019	11/18/2019	N	(S) Benzoic acid, 2,4-dichloro-5-fluoro-, ethyl ester.
P–19–0117	11/4/2019	10/18/2019	N	(G) Polycyclic amine, reaction products with polyalkylalkene, polymers.
P–19–0130	10/30/2019	10/23/2019	N	(G) Aminohydroxy salt.

* The term 'Approved' indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission.

In Table III of this unit, EPA provides the following information (to the extent such information is not subject to a CBI claim) on the test information that has been received during this time period: The EPA case number assigned to the test information; the date the test information was received by EPA, the type of test information submitted, and chemical substance identity.

TABLE III—TEST INFORMATION RECEIVED FROM 11/01/2019 TO 11/30/2019

Case No.	Received date	Type of test information	Chemical substance
P–09–0644	11/4/2019	Annual Analytical Report	(G) Substituted alkyl phosphate ester.
P–16–0543	11/4/2019 11/18/2019	Exposure Monitoring Report	(G) Halogenophosphoric acid metal salt.
P–16–0593	11/4/2019	Particle Size Distribution Study and Surface Tension Study (OECD Test Guideline 115).	(G) Aromatic Polyester Polyol.
P–17–0195	11/4/2019 11/20/2019	Combined Repeated Dose and Reproductive/Development Test of [Claimed CBI] by Oral Administration in Rats (OECD Test Guideline 422), Clinical signs table, Plasma concentration of total T4 in rats table. Evaluation of DNA Repair Inducing Ability of [CBI] in Male Rat Hepatocytes (in vivo Rat Hepatocyte DNA-Repair Assay) (OECD Test Guideline 486).	(G) 1,3-Propanediol, 2-methylene- substituted.
P–18–0027	11/7/2019	Substance Identifiers	(G) 2-Propenoic acid, 2-alkyl-, 2-(dialkylamino)alkyl ester, polymer with alpha-(2-alkyl-1-oxo-2-alken-1-yl)-omega-methoxypoly(oxy-1,2-alkanediyl).

TABLE III—TEST INFORMATION RECEIVED FROM 11/01/2019 TO 11/30/2019—Continued

Case No.	Received date	Type of test information	Chemical substance
P–18–0141	11/18/2019	Evaluation of the Ability of [CBI] to Induce Chromosome Aberration in Cultured Peripheral Human Lymphocytes (OECD Test Guideline 473), Activated Sludge Respiration Inhibition Test with [CBI] (OECD Test Guideline 209), DEREK Prediction on Skin Sensitization of [CBI],. Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OECD Test Guideline 422), Determination of Physico-Chemical Properties of [CBI] (OECD Test Guideline s101, 102, 103, 104, 109), *In vitro* Skin Corrosion Test with using a Human Skin Model (OECD Test Guideline 431), Ready Biodegeradability (OECD Test Guideline 301B), Evaluation of the Eye Hazard Potential of using the Bovine Corneal Opacity and Permeability Test (OECD Test Guideline 437), Acute Oral Toxicity (OCED Test Guideline 423), *In Vitro* Skin Irritation (OECD Test Guideline 439), Acute Inhalation Toxicity (OECD Test Guideline 403).	(G) Ethyl modified lactam.
P–18–0293	11/7/2019	Skin Sensitization Test (Local Lymph Node Assay) (OECD Test Guideline 429).	(S) propanedioic acid, 2-methylene-, 1,3-dihexyl ester.
P–18–0294	11/7/2019	Skin Sensitization Test (Local Lymph Node Assay) (OECD Test Guideline 429).	(S) propanedioic acid, 2-methylene-, 1,3-dicyclohexyl ester.
P–18–0350	11/26/2019	Acute Oral Toxicity (OECD Test Guideline 401), Hydrolysis as a Function of pH (OECD Test Guideline 111), Read Across Justification.	(G) Aqueous methacrylamido modified polysiloxane.
P–19–0041	11/26/2019 Submitted	Acute Toxicity to Fish Mitigated by Humic Acid.	(G) Alkyl diester, polymer with (dialkylamino alkyl) amine and bis(halogenated alkyl) ether.

If you are interested in information that is not included in these tables, you may contact EPA's technical information contact or general information contact as described under **FOR FURTHER INFORMATION CONTACT** to access additional non-CBI information that may be available.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: January 29, 2020.

Pamela Myrick,

Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2020–03146 Filed 2–14–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2019–0075; FRL–9992–86]

Certain New Chemicals; Receipt and Status Information for December 2019

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is required under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to make information publicly available and to publish information in the **Federal Register** pertaining to submissions under TSCA Section 5, including notice of receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN) or Microbial Commercial Activity Notice (MCAN), including an amended notice or test information; an exemption application (Biotech exemption); an application for a test marketing exemption (TME), both pending and/or concluded; a notice of commencement (NOC) of manufacture (including import) for new chemical substances; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review. This document covers the period from 12/01/2019 to 12/31/2019.

DATES: Comments identified by the specific case number provided in this document must be received on or before March 19, 2020.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2019–0075, and the specific case number for the chemical substance related to your comment, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Jim Rahai, Information Management Division (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–8593; email address: *rahai.jim@epa.gov.*

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

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

This document provides the receipt and status reports for the period from 12/01/2019 to 12/31/2019. The Agency is providing notice of receipt of PMNs, SNUNs and MCANs (including amended notices and test information); an exemption application under 40 CFR part 725 (Biotech exemption); TMEs, both pending and/or concluded; NOCs to manufacture a new chemical substance; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review.

EPA is also providing information on its website about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its website at: *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices.* This information is updated on a weekly basis.

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

Under the TSCA, 15 U.S.C. 2601 *et seq.,* a chemical substance may be either an ''existing'' chemical substance or a ''new'' chemical substance. Any chemical substance that is not on EPA's TSCA Inventory of Chemical Substances (TSCA Inventory) is classified as a ''new chemical substance,'' while a chemical substance that is listed on the TSCA Inventory is classified as an ''existing chemical substance.'' (See TSCA section 3(11).) For more information about the TSCA Inventory go to: *https://www.epa.gov/tsca-inventory.*

Any person who intends to manufacture (including import) a new chemical substance for a non-exempt commercial purpose, or to manufacture or process a chemical substance in a non-exempt manner for a use that EPA has determined is a significant new use, is required by TSCA section 5 to provide EPA with a PMN, MCAN or SNUN, as appropriate, before initiating the activity. EPA will review the notice, make a risk determination on the chemical substance or significant new use, and take appropriate action as described in TSCA section 5(a)(3). TSCA section 5(h)(1) authorizes EPA to allow persons, upon application and under appropriate restrictions, to manufacture or process a new chemical substance, or a chemical substance subject to a significant new use rule (SNUR) issued under TSCA section 5(a)(2), for ''test marketing'' purposes, upon a showing that the manufacture, processing, distribution in commerce, use, and disposal of the chemical will not present an unreasonable risk of injury to health or the environment. This is referred to as a test marketing exemption, or TME. For more information about the requirements applicable to a new chemical go to: *http://www.epa.gov/oppt/newchems.*

Under TSCA sections 5 and 8 and EPA regulations, EPA is required to publish in the **Federal Register** certain information, including notice of receipt of a PMN/SNUN/MCAN (including amended notices and test information); an exemption application under 40 CFR part 725 (biotech exemption); an application for a TME, both pending and concluded; NOCs to manufacture a new chemical substance; and a periodic status report on the new chemical substances that are currently under EPA review or have recently concluded review.

C. Does this action apply to me?

This action provides information that is directed to the public in general.

D. Does this action have any incremental economic impacts or paperwork burdens?

No.

E. What should I consider as I prepare my comments for EPA?

1. *Submitting confidential business information (CBI).* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. Status Reports

In the past, EPA has published individual notices reflecting the status of TSCA section 5 filings received, pending or concluded. In 1995, the Agency modified its approach and streamlined the information published in the **Federal Register** after providing notice of such changes to the public and an opportunity to comment (See the **Federal Register** of May 12, 1995, (60 FR 25798) (FRL–4942–7). Since the passage of the Lautenberg amendments to TSCA in 2016, public interest in information on the status of section 5 cases under EPA review and, in particular, the final determination of such cases, has increased. In an effort to be responsive to the regulated community, the users of this information, and the general public, to comply with the requirements of TSCA, to conserve EPA resources and to streamline the process and make it more timely, EPA is providing information on its website about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its website at: *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices.* This information is updated on a weekly basis.

III. Receipt Reports

For the PMN/SNUN/MCANs that have passed an initial screening by EPA during this period, Table I provides the following information (to the extent that such information is not subject to a CBI claim) on the notices screened by EPA during this period: The EPA case number assigned to the notice that indicates whether the submission is an

initial submission, or an amendment, a notation of which version was received, the date the notice was received by EPA, the submitting manufacturer (*i.e.,* domestic producer or importer), the potential uses identified by the manufacturer in the notice, and the chemical substance identity.

As used in each of the tables in this unit, (S) indicates that the information in the table is the specific information provided by the submitter, and (G) indicates that this information in the table is generic information because the specific information provided by the submitter was claimed as CBI. Submissions which are initial submissions will not have a letter following the case number. Submissions which are amendments to previous submissions will have a case number followed by the letter ''A'' (*e.g.,* P–18–1234A). The version column designates submissions in sequence as ''1'', ''2'', ''3'', etc. Note that in some cases, an initial submission is not numbered as version 1; this is because earlier version(s) were rejected as incomplete or invalid submissions. Note also that future versions of the following tables may adjust slightly as the Agency works to automate population of the data in the tables.

TABLE I—PMN/SNUN/MCANS APPROVED * FROM 12/01/2019 TO 12/31/2019

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
J–20–0002	1	11/25/2019	CBI	(G) Production of a chemical	Microorganism with chromosomally-borne genetic modifications for the production of a chemical.
P–16–0486A	5	11/22/2019	CBI	(G) Site-limited intermediate in the production of a refrigerant precursor.	(G) Polychloropropane.
P–16–0539A	5	12/3/2019	CBI	(G) photolithography	(G) Organic sulfonate compound.
P–17–0239A	7	12/11/2019	CBI	(G) Adhesive for open non-descriptive use	(G) Substituted carboxylic acid, polymer with 2,4-diisocyanato-1-methylbenzene, hexanedioic acid, alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], 1,1′-methylenebis[4-isocyanatobenzene], 2,2′-oxybis[ethanol], 1,1′-oxybis[2-propanol] and 1,2-propanediol.
P–17–0245A	7	12/12/2019	CBI	(G) Adhesive for open, non-dispersive use	(G) Unsaturated polyfluoro ester.
P–17–0282A	11	12/11/2019	Elantas PDG, Inc	(S) This is a component of a mixture that is used as an impregnating varnish for stators and motors.	(S) Isocyanic acid, polymethylenepolyphenylene ester, caprolactam- and phenol-blocked.
P–17–0405A	8	12/6/2019	CBI	(G) Oil and gas well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0406A	7	12/6/2019	CBI	(G) Oil and gas well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0407	6	12/6/2019	CBI	(G) Well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0408	5	12/6/2019	CBI	(G) Well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0409	6	12/6/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0410	5	12/6/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0411	5	12/6/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0412	5	12/6/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0414	5	12/6/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid.
P–17–0415	6	12/6/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid.
P–17–0416	6	12/6/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid.
P–17–0417	6	12/6/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid.
P–17–0418A	6	12/6/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid.
P–17–0420A	7	12/6/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid.
P–17–0421A	6	12/6/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid.
P–17–0422A	6	12/6/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid.
P–17–0423	5	12/6/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0441	5	12/9/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0442	5	12/9/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0443A	6	12/9/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0444	4	12/11/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0445A	7	12/9/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0446A	6	12/9/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0447	6	12/9/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0448	5	12/9/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0449	5	12/9/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0450	5	12/9/2019	CBI	(G) Monitor well performance	(G) Halogenated benzoic acid.
P–18–0133A	3	12/2/2019	CBI	(G) component in hydraulic fracturing fluids.	(G) Polyol adduct of bisaldehyde.
P–18–0253A	3	11/22/2019	UBE America, Inc	(G) Extrusion and Injection Molding Polymer.	(S) Dodecanoic acid, 12-amino-, homopolymer.
P–18–0254A	3	11/22/2019	UBE America, Inc	(G) Extrusion and Injection Molding Polymer.	(G) Hexanedioic acid, polymer with 12-aminododecanoic acid and a polyetheramine.
P–18–0255A	3	11/22/2019	UBE America, Inc	(G) Recreational equipment	(S) Dodecanoic acid, 12-amino-, polymer with hexahydro-2H-azepin-2-one.
P–18–0267A	4	11/21/2019	CBI	(G) curing agent	(G) Branched alkanoic acid, epoxy ester, reaction products with monocyclic dialkylamine and polycyclic alcohol epoxy polymer.
P–18–0268A	4	11/21/2019	CBI	(G) curing agent	(G) Branched alkanoic acid, epoxy ester, reaction products with monocyclicdialkanamine and polycyclic dialkanol ether polymer.
P–18–0269A	4	11/21/2019	CBI	(G) curing agent	(G) Branched alkanoic acid, epoxy ester, reaction products with monocyclicalkanamine, polycyclic alcohol ether homopolymer, and polycyclic alcohol epoxy polymer.
P–18–0273A	2	12/11/2019	CBI	(G) Used in polymer manufacturing	(S) 1,4-Cyclohexanedicarboxylic acid, 1,4-bis(2-ethylhexyl) ester.

TABLE I—PMN/SNUN/MCANS APPROVED * FROM 12/01/2019 TO 12/31/2019—Continued

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
P–18–0287A	9	12/4/2019	CBI	(G) Company plans to produce ''tires, wastes, pyrolyzed, condensate oil fraction'' (hereafter referred to as syn oil) (CASRN: 1312024–02–4) from scrap tire materials.	(G) Synthetic oil from tires.
P–18–0300A	3	12/4/2019	CBI	(S) Additive for automatic dishwashing detergent.	(G) Heteromonocycle, alkenoic 1:1 salt, polymer with alpha-(2-methyl-1-oxo-2-propen-1-y)l-omegamethoxypoly(oxy-1,2-ethanediyl) and methyl-alkenoic acid.
P–18–0345A	2	12/10/2019	Chitec Technology Co., Ltd.	(S) R-gen 990 is a liquid aminoketone-based photoinitator (PI) intended for use as an ultraviolet (UV) curing agent in highly pigmented inks, photo-resists, and masks.	(S) 1-Butanone, 2-(dimethylamino)-1-[4-(2-ethyl-2-methyl-3-oxazolidinyl)phenyl]-2-(phenylmethyl)-.
P–18–0350A	2	12/4/2019	Evonik Corporation	(S) Additive in water-borne UV-curable coatings,(S) Filler & pigment treatment,(S) Glass fiber treatment.	(G) Aqueous methacrylamido modified polysiloxane.
P–18–0359A	3	12/10/2019	CBI	(G) Molded or extruded items	(G) Methoxy Vinyl Ether- Vinylidene Fluoride polymer.
P–18–0367A	3	12/9/2019	CBI	(S) Acid-modified polyether used as a wetting and dispersing additive for pigments in industrial paints and coatings.	(G) Acid-modified polyether.
P–19–0052A	5	12/11/2019	Evonik Corporation	(S) Hard Surface Cleaner,(S) Component of Laundry Detergent.	(S) Poly(oxy-1,2-ethanediyl), alpha-nonyl-omega-hydroxy-, branched and linear.
P–19–0055A	3	12/9/2019	Rahn USA, Corp	(S) The PMN is solely used as a photo initiator within UV curable coating/ink formulations.	(S) 1,3-propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with oxirane, 4-(dimethylamino)benzoate.
P–19–0083A	2	12/3/2019	KX Technologies, LLC.	(G) Activated carbon for water purification	(G) Charcoal, coconut shell, reaction products with cyclic amine.
P–19–0135A	4	12/10/2019	CBI	(G) Lubricant Additive	(G)Alkyl polyoxyethylene ethers, carboxymethylated.
P–19–0146A	3	11/25/2019	CBI	(G) Reagent used to introduce deuterium to the substrate chemical.	(G) Modified dimethyl sulfoxide.
P–19–0148A	2	12/13/2019	CBI	(G) Fertilizer ingredient	(G) Iron, complexes with ethylenediamine-4-hydroxycarbomonocycle hetero-acid-2-oxoacetic acid reaction products, potassium salts.
P–19–0149A	2	12/13/2019	CBI	(G) Fertilizer ingredient	(G) Iron, complexes with ethylenediamine-4-hydroxycarbomonocycle hetero-acid potassium salt (1:1)-potassium 2-oxoacetate (1:1) reaction products, potassium salts.
P–19–0150A	2	12/13/2019	CBI	(G) Fertilizer ingredient	(G) Iron, complexes with ethylenediamine-4-hydroxycarbomonocycle hetero-acid-2-oxoacetic acid reaction products, sodium salts.
P–19–0151A	2	12/13/2019	CBI	(G) Fertilizer ingredient	(G) Iron, complexes with ethylenediamine-4-hydroxycarbomonocycle hetero-acid sodium salt (1:1)-sodium 2-oxoacetate (1:1) reaction products, sodium salts.
P–19–0152A	3	11/21/2019	UBE America, Inc	(G) Pre-polymer for polyurethane roll covers.	(G) alkaneic acid, dialkyl ester polymer with alkanediol, [[(isocyanatocarbomonocycl-e)alkyl)carbomonocycle)carbamate.
P–19–0159A	5	12/6/2019	CBI	(G) As Catalyst in Industrial sector	(G) Titanium (4+) hydroxy-alkylcarboxylate salt complex.
P–19–0159A	6	12/13/2019	CBI	(G) As Catalyst in Industrial sector	(G) Titanium (4+) hydroxy-alkylcarboxylate salt complex.
P–19–0174	3	12/11/2019	International Lubricants, Inc.	(G) Phosphorus antiwear compound	(G) Octadecanoic acid, (alkylphosphinyl), polyol ester.
P–20–0009A	3	12/11/2019	Resinate Materials Group, Inc.	(S) Intermediate for use in the manufacture of polymers.	(G) Waste plastics, poly(ethylene terephthalate), depolymd. with polyol, polymers with alkanedioic acid and alkanoic acid.
P–20–0011A	4	12/2/2019	CBI	(G) Light stabilizer	(G) Tetraoxaspiro[5.5]alkyl-3,9-diylbis(alkyl-2,1-diyl) bis(2-cyano-3-(3,4-dimethoxyphenyl)acrylate).
P–20–0012A	5	12/12/2019	CBI	(G) Ink Additive	(G) Polyol, polymer with alkyl diisocyanate, alkyl substituted heterocycle blocked.
P–20–0018	2	11/26/2019	CBI	(G) Component in candles	(G) Fatty acid dimers, polymers with glycerol and triglycerides.
P–20–0019	2	11/26/2019	CBI	(G) Component in candles	(G) Fatty acid dimers, polymers with glycerol and triglycerides.
P–20–0020	2	11/26/2019	CBI	(G) Component in candles	(G) Fatty acid dimers, polymers with glycerol and triglycerides.
P–20–0021	2	11/26/2019	CBI	(G) Component in candles	(G) Fatty acid dimers, polymers with glycerol and fatty acids.
P–20–0022	2	12/9/2019	CBI	(G) Fuel additive for combustion improver	(G) Polyalkoxycarbopolycycle hydroxy.
P–20–0024	3	12/4/2019	CBI	(G) Dispersant polymer for coatings	(G) Phenol-formaldehyde polymer with amino-oxirane copolymer and nitrobenzoates.
P–20–0026	2	12/20/2019	GE Healthcare	(S) The new monomer is isolated and used for subsequent polymerization.	(G) N-alkyl heteromonocyclic diphenolamide.
P–20–0029	2	12/18/2019	KURARAY America, Inc.	(G) Oil soluble additive	(S) Octanal, 7(or 8)-formyl-.

TABLE I—PMN/SNUN/MCANS APPROVED * FROM 12/01/2019 TO 12/31/2019—Continued

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
P–20–0030	1	12/16/2019	CBI	(S) Plasticizer for Plastisols, and Plasticizer in caulks and sealants.	(G) Hexanedioic acid, alkyl ester.
P–20–0032	1	12/18/2019	Engineered Bonded Structures and Composites.	(S) Talathol PO3, the material for which this notice is filed, is intended to be used as a copolymer in the production of urethane foam or coating.	(G) Polyethylene terephthalate polyol.
P–20–0035	1	12/19/2019	CBI	(G) Colorant	(G) Substituted aromatic, 3,3′-[[6-[(substituted alkyl amino)]-1,3,5-triazine-2,4-diyl]bis[imino[2-(substituted)-5-[substituted alkoxy]-4,1-phenylene]-2,1- diazenediyl]]bis[substituted, sodium salt].
P–20–0038	1	12/23/2019	Nissan Chemical Houston Corporation.	(S) PMN substance will be used as resist compound for semiconductor manufacture.	(S) 1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris[3-(2-oxiranyl)propyl]-.

* The term 'Approved' indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission prior to the start of the 90-day review period, and in no way reflects the final status of a complete submission review.

In Table II of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the NOCs that have passed an initial screening by EPA during this period: The EPA case number assigned to the NOC including whether the submission was an initial or amended submission, the date the NOC was received by EPA, the date of commencement provided by the submitter in the NOC, a notation of the type of amendment (*e.g.,* amendment to generic name, specific name, technical contact information, etc.) and chemical substance identity.

TABLE II—NOCS APPROVED * FROM 12/01/2019 TO 12/31/2019

Case No.	Received date	Commencement date	If amendment, type of amendment	Chemical substance
P–16–0132A	12/12/2019	10/24/2019	Withdrew CBI claim.	(S) Oxirane, 2-methyl-, polymer with oxirane, mono-c16-18-alkyl ethers, phosphates.
P–16–0388	12/3/2019	11/25/2019	N	(S) Amines, n-(3-aminopropyl)-n-tallow alkyltrimethylenedi-, polymers with bisphenol A and epichlorohydrin.
P–16–0470	11/28/2019	11/19/2019	N	(S) 2,7-Nonadien-4-ol, 4,8-dimethyl-.
P–16–0572A	12/10/2019	9/19/2019	Generic chemical name.	(G) Fatty acids, tall oil, reaction products with polyalkylene-polysubstituted-terephthalic acid polymer.
P–17–0362	12/11/2019	11/12/2019	N	(G) Aliphatic phosphoric amide ester.
P–18–0125	11/26/2019	11/18/2019	N	(S) Acetic acid, 2-oxo-, sodium salt (1:1).
P–18–0155	12/4/2019	11/20/2019	N	(G) Crosslinked polymer of alkyl acrylamides, acrylate esters, and alkyl acrylamide sulfonate salt.
P–18–0156	12/4/2019	11/20/2019	N	(G) Crosslinked polymer of alkyl acrylamides, acrylate esters, and alkyl acrylamide sulfonic acid.
P–18–0295	11/27/2019	11/5/2019	N	(S) 1,3-Butanediol, (3R)-.
P–18–0300	12/4/2019	11/20/2019	N	(G) Heteromonocycle, alkenoic 1:1 salt, polymer with .alpha.-(2-methyl-1-oxo-2-propen-1-yl)-.omega.-methoxypoly(oxy-1,2-ethanediyl) and methyl-alkenoic acid.
P–18–0321A	12/5/2019	10/23/2019	Withdrew CBI claim.	(S) Poly(oxy-1,2-ethanediyl), alpha,alpha′-(1-methyl-1,2-ethanediyl)bis[omega-hydroxy-.
P–19–0065	12/9/2019	11/15/2019	N	(S) 2lamda5,4lamda5,6lamda5—1,3,5,2,4,6 triazatriphosphorine, 2,2,4,4,6,6 -hexaphenoxy-.
P–19–0108	12/3/2019	11/18/2019	N	(S) Benzoic acid, 2-chloro-4-methyl-, ethyl ester.
P–19–0120	12/11/2019	11/21/2019	N	(G) Alkenoic acid, polymer with alkanediyl bis substituted alkylene bis heteromonocycle, substituted carbomonocycle and (alkylalkenyl) carbomonocycle, alkali metal salt.

* The term 'Approved' indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission.

In Table III of this unit, EPA provides the following information (to the extent such information is not subject to a CBI claim) on the test information that has been received during this time period: The EPA case number assigned to the test information; the date the test information was received by EPA, the type of test information submitted, and chemical substance identity.

TABLE III—TEST INFORMATION RECEIVED FROM 12/01/2019 TO 12/31/2019

Case No.	Received date	Type of test information	Chemical substance
L–18–0168	11/25/2019	Particle Size Distribution Study	(G) Aromatic carboxylic acid, 2-[2-(6-amino-1-hydroxy-3-sulfo-2-aromaticyl)diazenyl]-, reaction products with 4-[[7-[2-(4-amino-2-alkoxyaromaticyl)diazenyl]-8-hydroxy-6-sulfo-2-aromaticyl]amino]aromatic carboxylic acid, 4-[2-(4-aminoaromaticyl)diazenyl]aromaticsulfonic acid, metal sulfate, 2,2′-(1,2-alkenediyl)bis[5-nitroaromaticsulfonic acid] and sodium hydroxide.
P–06–0489	12/14/2019	Annual Impurity Report	(G) Fluoroalkyl methacrylate copolymer.
P–06–0494	12/14/2019	Annual Impurity Report	(G) Fluoroalkyl methacrylate copolymer.
P–06–0576	12/14/2019	Annual Impurity Report	(G) Fluoroalkyl acrylate copolymer.
P–06–0586	12/14/2019	Annual Impurity Report	(G) Fluoroalkyl methacrylate copolymer.
P–07–0447	12/14/2019	Annual Impurity Report	(G) Fluoroalkyl acrylate copolymer.
P–08–0222	12/14/2019	Annual Impurity Report	(G) Fluoroalkyl acrylate copolymer.
P–09–0037	12/14/2019	Annual Impurity Report	(G) Fluoroalkyl methacrylate copolymer.
P–09–0511	12/14/2019	Annual Impurity Report	(G) Fluoroalkyl acrylate copolymer.
P–10–0317	12/14/2019	Annual Impurity Report	(G) Fluoroalkyl acrylate copolymer.
P–13–0646	12/14/2019	Annual Impurity Report	(G) Fluoroalkyl acrylate copolymer.
P–13–0647	12/14/2019	Annual Impurity Report	(G) Fluoroalkyl acrylate copolymer.
P–13–0648	12/14/2019	Annual Impurity Report	(G) Fluoroalkyl acrylate copolymer.
P–13–0649	12/14/2019	Annual Impurity Report	(G) Fluoroalkyl acrylate copolymer.
P–13–0678	12/14/2019	Annual Impurity Report	(G) Fluoroalkyl methacrylate copolymer.
P–13–0679	12/14/2019	Annual Impurity Report	(G) Fluoroalkyl acrylate copolymer.
P–15–0154	12/14/2019	Annual Impurity Report	(G) Fluoroalkyl acrylate copolymer.
P–16–0543	12/12/2019	Exposure Monitoring Report	(G) Halogenophosphoric acid metal salt.
P–17–0005	12/09/2019	28-day (Subacute) Inhalation Toxicity Study (OECD Test Guideline 412).	(S) 1-tetradecene homopolymer hydrogenated.
P–17–0343A	12/03/2019	Ready Biodegradability of a Test Substance Based on OECD Method 301A, Acute Toxicity Test Freshwater Invertebrate and Vertebrate, Acute Oral Toxicity Study in Rats, Dermal and Eye Irritation Study.	(G) Modified benzimidazole.
P–17–0343A	12/03/2019	Ready Biodegradability of a Test Substance Based on OECD Method 301A, Acute Toxicity Test Freshwater Invertebrate and Vertebrate, Acute Oral Toxicity Study in Rats, Dermal and Eye Irritation Study.	(G) Modified benzimidazole salt.
P–18–0293	12/05/2019	*In vitro* Skin Corrosion Test with Chemilian H4000 XP using a Human Skin Model, In vitro Skin Irritation Test with Chemilian L3000 XP using a Human Skin Model.	(S) Propanedioic acid, 2-methylene-, 1,3-dihexyl ester.
P–18–0303	12/09/2019	Aquatic Toxicity Acute Base set (OECD Test Guideline 201, 202, 203).	(G) 2-propenoic acid, polymer with aliphatic cyclic epoxide.
P–18–0365	12/13/2019	Exposure Monitoring Report	(G) Starch, carboxymethyl ether, sodium salt, polymer with polycarboxylic acid.
P–18–0366	12/13/2019	Exposure Monitoring Report	(G) Starch, carboxymethyl ether, sodium salt, polymer with mixed polycarboxylic acids.
P–19–0038	12/16/2019	Water solubility Study (OECD Test Guideline 105), Partition Coefficient Study (OECD Test Guideline 107), Analytical Method Validation of Fatty acids, coco, iso-Bu esters, Validation of the analytical methods.	(S) Fatty acids, coco, iso-bu esters.
P–19–0041	11/25/2019	Algal Growth Inhibition Test, Acute Toxicity to Fish Mitigated by Humic Acid.	(G) Alkyl diester, polymer with (dialkylamino alkyl) amine and bis(halogenated alkyl) ether.
P–19–0147	12/12/2019	Vapor Pressure by Isoteniscope (ASTM D2879)	(G) Alkoxylated butyl alkyl ester.

If you are interested in information that is not included in these tables, you may contact EPA's technical information contact or general information contact as described under **FOR FURTHER INFORMATION CONTACT** to access additional non-CBI information that may be available.

(Authority: 15 U.S.C. 2601 *et seq.*)

Dated: January 31, 2020.

Megan Carroll,

Acting Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2020–03105 Filed 2–14–20; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0185, OMB 3060–0627, OMB 3060–0837 and OMB 3060–0928; FRS 16485]

Information Collections Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before April 20, 2020. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0185.

Title: Section 73.3613, Availability of Contracts.

Form Number: N/A.

Respondents: Business or other for-profit entities and Not-for-profit institutions.

Number of Respondents and Responses: 2,400 respondents; 2,400 responses.

Estimated Time per Response: 0.25 to 0.5 hours.

Frequency of Response: On-occasion reporting requirement, Recordkeeping requirement, Third-party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in sections 154(i) and 303 the Communications Act of 1934, as amended.

Total Annual Burden: 975 hours.

Total Annual Cost: $ 135,000.

Nature and Extent of Confidentiality: There is no need for confidentiality with this information collection.

Privacy Act: No impact(s).

Needs and Uses: The information collection requirements included under OMB Control Number 3060–0185 require that commercial and noncommercial AM, FM, TV, and international broadcast stations make station contracts and other documents available to the FCC as set forth in 47 CFR 73.3613.

OMB Control Number: 3060–0627.

Title: FCC Form 302–AM, Application for AM Broadcast Station License.

Form Number: FCC Form 302–AM.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, not for profit institutions.

Number of Respondents and Responses: 380 respondents and 380 responses.

Estimated Time per Response: 4–20 hours.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: 2,800 hours.

Total Annual Cost: $5,684,350.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority is contained in Sections 154(i), 303 and 308 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Impact Assessment(s): No impact(s).

Needs and Uses: Licenses and permittees of AM broadcast stations are required to file FCC Form 302–AM to obtain a new or modified station license, and/or to notify the Commission of certain changes in the licensed facilities of these stations. Additionally, when changes are made to an AM station that alter the resistance of the antenna system, a licensee must initiate a determination of the operating power by the direct method. The results of this are reported to the Commission using the FCC 302–AM.

OMB Control No.: 3060–0837.

Title: FCC Form 2100, Application for Media Bureau Audio and Video Service Authorization, Schedule B (Former FCC Form 302–DTV), Section 73.3700(b)(3), Section 73.3700(h)(2) and Section 73.3800.

Form No.: FCC Form 2100, Schedule B.

Type of Review: Extension of a currently approved information collection.

Respondents: Business or other for-profit entities; Not for profit institutions.

Number of Respondents and Responses: 975 respondents and 975 responses.

Estimated Time per Response: 2 hours.

Frequency of Response: One-time reporting requirement and on occasion reporting requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Sections 154(i), 307, 308, 309, and 319 of the Communications Act of 1934, as amended; the Community Broadcasters Protection Act of 1999, Public Law 106–113, 113 Stat. Appendix I at pp. 1501A–594–1501A–598 (1999) (codified at 47 U.S.C. 336(f)); and the Middle Class Tax Relief and Job Creation Act of 2012, Public Law 112–96, 6402 (codified at 47 U.S.C. 309(j)(8)(G)), 6403 (codified at 47 U.S.C. 1452), 126 Stat. 156 (2012) (Spectrum Act).

Total Annual Burden: 1,950 hours.

Annual Cost Burden: $585,945.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: FCC Form 2100, Schedule B (formerly FCC Form 302–DTV) is used by licensees and permittees of full power broadcast stations to obtain a new or modified station license and/or to notify the Commission of certain changes in the licensed facilities of those stations. It may be used: (1) To cover an authorized construction permit (or auxiliary antenna), provided that the facilities have been constructed in compliance with the provisions and conditions specified on the construction permit; or (2) To implement modifications to existing licenses as permitted by 47 CFR Sections 73.1675(c) or 73.1690(c).

The information collection requirements contained in Section 73.3700(b)(3) require the licensee of each channel sharee station and channel sharer station to file an application for a license for the shared channel using FCC Form 2100 Schedule B (for a full power station) or F (for a Class A station) within six months of the date that the channel sharee station licensee receives its incentive payment pursuant

to section 6403(a)(1) of the Spectrum Act.

The information collection requirements contained in Section 73.3700(h)(2) state that, upon termination of the license of a party to a CSA, the spectrum usage rights covered by that license may revert to the remaining parties to the CSA. Such reversion shall be governed by the terms of the CSA in accordance with paragraph (h)(4)(E) of this section. If upon termination of the license of a party to a CSA only one party to the CSA remains, the remaining licensee may file an application to change its license to non-shared status using FCC Form 2100, Schedule B (for a full power licensee) or F (for a Class A licensee).

Lastly, Section 73.3800 allows full power television stations to channel share with other full power stations, Class A, LPTV and TV translator stations outside of the incentive auction context. Full power stations file FCC Form 2100, Schedule B in order to complete the licensing of their shared channel.

OMB Control No.: 3060–0928.

Title: FCC Form 2100, Application for Media Bureau Audio and Video Service Authorization, Schedule F (Formerly FCC 302–CA); 47 CFR 73.6028; Section 73.3700(b)(3); Section 73.3700(h)(2) and Section 73.3572(h).

Form No.: FCC Form 2100, Schedule F.

Type of Review: Extension of a currently approved information collection.

Respondents: Business or other for-profit entities; Not for profit institutions; State, local or Tribal Government.

Number of Respondents and Responses: 975 respondents and 975 responses.

Estimated Time per Response: 2 hours.

Frequency of Response: One-time reporting requirement and on occasion reporting requirement.

Total Annual Burden: 1,950 hours.

Annual Cost Burden: $307,125.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The FCC Form 2100, Schedule F is used by Low Power TV (LPTV) stations that seek to convert to Class A status; existing Class A stations seeking a license to cover their authorized construction permit facilities; and Class A stations entering into a channel sharing agreement. The FCC Form 2100, Schedule F requires a series of certifications by the Class A applicant as prescribed by the Community Broadcasters Protection Act of 1999 (CBPA). Licensees will be required to provide weekly announcements to their listeners: (1) Informing them that the applicant has applied for a Class A license and (2) announcing the public's opportunity to comment on the application prior to Commission action.

Information Collection Requirements

Section 73.6028 permits Class A stations to seek approval to share a single television channel with LPTV, TV translator, full power and Class A television stations. Class A stations interested in terminating operations and sharing another station's channel must submit FCC Form 2100 Schedule F in order to complete the licensing of their channel sharing arrangement.

Section 73.3700(b)(3) requires the licensee of each channel sharee station and channel sharer station to file an application for a license for the shared channel using FCC Form 2100 Schedule B (for a full power station) or F (for a Class A station) within six months of the date that the channel sharee station licensee receives its incentive payment pursuant to section 6403(a)(1) of the *Spectrum Act.*

Section 73.3700(h)(2) states that, upon termination of the license of a party to a channel sharing assignees (CSA), the spectrum usage rights covered by that license may revert to the remaining parties to the CSA. Such reversion shall be governed by the terms of the CSA in accordance with 47 CFR 73.3700(h)(4)(E). If upon termination of the license of a party to a CSA only one party to the CSA remains, the remaining licensee may file an application to change its license to non-shared status using FCC Form 2100, Schedule B (for a full power licensee) or F (for a Class A licensee).

Section 73.3572(h)—Class A TV station licensees shall file a license application for either the flash cut channel or the digital companion channel they choose to retain for post-transition digital operations. Class A TV stations will retain primary, protected regulatory status on their desired post-transition digital channel. Class A TV applicants must certify that their proposed post-transition digital facilities meet all Class A TV interference protection requirements.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2020–03136 Filed 2–14–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Senior Executive Service; Performance Review Board

AGENCY: Federal Mine Safety and Health Review Commission.

ACTION: Notice.

SUMMARY: This notice announces the appointment of the members of the Performance Review Board (PRB) for the Federal Mine Safety and Health Review Commission. The PRB reviews the performance appraisals of career and non-career senior executives. The PRB makes recommendations regarding proposed performance appraisals, ratings, bonuses, pay adjustments, and other appropriate personnel actions.

DATES: Effective on February 18, 2020.

FOR FURTHER INFORMATION CONTACT: Lisa Boyd, Executive Director, Federal Mine Safety and Health Review Commission, (202) 434–9910.

SUPPLEMENTARY INFORMATION: This Notice announces the appointment of the following primary and alternate members to the Federal Mine Safety and Health Review Commission PRB:

Primary Members

David Copenhaver, Assistant Commissioner, Office of Shared Services, Bureau of the Fiscal Service

Jason Hill, Deputy Assistant Commissioner, Office of Shared Services, Bureau of the Fiscal Service

Marisa Schmader, Deputy Assistant Commissioner, Fiscal Accounting Support and Outreach, Bureau of the Fiscal Service

Alternate Members

None.

Authority: 5 U.S.C. 4313(c)(4).

Lisa M. Boyd,

Executive Director, Federal Mine Safety and Health Review Commission.

[FR Doc. 2020–03070 Filed 2–14–20; 8:45 am]

BILLING CODE 6735–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or

the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than March 18, 2020.

A. Federal Reserve Bank of St. Louis (David L. Hubbard, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to *Comments.applications@stls.frb.org:*

1. *First Illinois Bancorp, Inc., East St. Louis, Illinois;* to acquire Rockwood Bancshares, Inc., and thereby indirectly acquire Rockwood Bank, both of Eureka, Missouri.

Board of Governors of the Federal Reserve System, February 12, 2020.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2020–03145 Filed 2–14–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Matching Program

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

ACTION: Notice of New Matching Program.

SUMMARY: In accordance with subsection (e)(12) of the Privacy Act of 1974, as amended, the Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) is providing notice of a new matching program between CMS and the Department of the Treasury (Treasury), Internal Revenue Services (IRS), ''Verification of Household Income and Family Size for Insurance Affordability Programs and Exemptions.''

DATES: The deadline for comments on this notice is March 19, 2020. The re-established matching program will commence not sooner than 30 days after publication of this notice, provided no comments are received that warrant a change to this notice. The matching program will be conducted for an initial term of 18 months (from approximately April 2020 to October 2021) and within 3 months of expiration may be renewed for one additional year if the parties make no change to the matching program and certify that the program has been conducted in compliance with the matching agreement.

ADDRESSES: Interested parties may submit comments on the new matching program to the CMS Privacy Officer by mail at: Division of Security, Privacy Policy & Governance, Information Security & Privacy Group, Office of Information Technology, Centers for Medicare & Medicaid Services, Location: N1–14–56, 7500 Security Blvd., Baltimore, MD 21244–1850, or *walter.stone@cms.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: If you have questions about the matching program, you may contact Anne Pesto, Senior Advisor, Marketplace Eligibility and Enrollment Group, Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services, at 410–786–3492, by email at *anne.pesto@cms.hhs.gov,* or by mail at 7500 Security Blvd., Baltimore, MD 21244.

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974, as amended (5 U.S.C. 552a) provides certain protections for individuals applying for and receiving federal benefits. The law governs the use of computer matching by federal agencies when records in a system of records (meaning, federal agency records about individuals retrieved by name or other personal identifier) are matched with records of other federal or non-federal agencies. The Privacy Act requires agencies involved in a matching program to:

1. Enter into a written agreement, which must be prepared in accordance with the Privacy Act, approved by the Data Integrity Board of each source and recipient federal agency, provided to Congress and the Office of Management and Budget (OMB), and made available to the public, as required by 5 U.S.C. 552a(o), (u)(3)(A), and (u)(4).

2. Notify the individuals whose information will be used in the matching program that the information they provide is subject to verification through matching, as required by 5 U.S.C. 552a(o)(1)(D).

3. Verify match findings before suspending, terminating, reducing, or making a final denial of an individual's benefits or payments or taking other adverse action against the individual, as required by 5 U.S.C. 552a(p).

4. Report the matching program to Congress and the OMB, in advance and annually, as required by 5 U.S.C. 552a(o) (2)(A)(i), (r), and (u)(3)(D).

5. Publish advance notice of the matching program in the **Federal Register** as required by 5 U.S.C. 552a(e)(12).

This matching program meets these requirements.

Barbara Demopulos,

Privacy Advisor, Division of Security, Privacy Policy and Governance, Information Security and Privacy Group, Office of Information Technology, Centers for Medicare & Medicaid Services.

Participating Agencies

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) is the recipient agency, and the Department of the Treasury (Treasury), Internal Revenue Services (IRS) is the source agency.

Authority for Conducting the Matching Program

The statutory authority for the matching program is 42 U.S.C. 18001.

Purpose(s)

The purpose of the matching program is to provide CMS with IRS return information which CMS and state-based administering entities (AEs) will use to verify household income and family size for applicants and enrollees receiving eligibility determinations and redeterminations for benefits including: enrollment in a Qualified Health Plan (QHP) or a state's Basic Health Plan (BHP) through the federally-facilitated Exchange (FFE) or a state-based Exchange (SBE); advance payments of the premium tax credit (APTC); a cost sharing reduction (CSR); Medicaid and the Children's Health Insurance Program (CHIP); and certain certificates of exemption.

Categories of Individuals

The individuals whose information will be used in the matching program are consumers (applicants and enrollees) who receive the eligibility determinations and redeterminations described in the preceding Purpose(s) section (in particular, taxpayers whose return information is requested from IRS to verify an applicant's or enrollee's household income and family size).

Categories of Records

The categories of records used in the matching program are identity information and return information (specifically, household income and family size information). To request return information from IRS, CMS will provide IRS with the relevant taxpayer's name, social security number (SSN), and relationship to the applicant(s) or enrollee(s) (*i.e.,* primary, spouse, or dependent). When IRS is able to match the SSN and name provided by CMS and return information is available, IRS will disclose to CMS the following items of return information with respect to that taxpayer:

1. SSN;

2. family size;

3. tax filing status;

4. modified adjusted gross income (MAGI);

5. taxable year with respect to which the preceding information relates or, if applicable, the fact that such information is not available; and

6. any other specified item of return information authorized pursuant to 26 U.S.C. 6103(1)(21) and its implementing regulations.

System(s) of Records

The records used in this matching program will be disclosed from the following systems of records, as authorized by routine uses published in the System of Records Notices (SORNs) cited below:

A. System of Records Maintained by CMS

- CMS Health Insurance Exchanges System (HIX), CMS System No. 09–70–0560, last published in full at 78 FR 63211 (Oct. 23, 2013), as amended at 83 FR 6591 (Feb. 14, 2018).

B. System of Records Maintained by IRS

- Customer Account Data Engine (CADE) Individual Master File, Privacy Act SOR Treasury/IRS 24.030, published at 80 FR 54064 (Sept. 8, 2015).

[FR Doc. 2020–03051 Filed 2–14–20; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3391–PN]

Medicare and Medicaid Programs: Application From the Joint Commission for Continued Approval of Its Hospital Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice acknowledges the receipt of an application from the Joint Commission for continued recognition as a national accrediting organization for hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 19, 2020.

ADDRESSES: In commenting, please refer to file code CMS–3391–PN. 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: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3391–PN, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3391–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Caecilia Blondiaux, (410) 786–2190.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a hospital provided certain requirements are met. Sections 1861(e) of the Social Security Act (the Act), establish distinct criteria for facilities seeking designation as a hospital. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 482 specify the minimum conditions that a hospital must meet to participate in the Medicare program.

Generally, to enter into an agreement, a hospital must first be certified by a state survey agency (SA) as complying with the conditions or requirements set forth in part 482 of our regulations. Thereafter, the hospital is subject to regular surveys by a SA to determine whether it continues to meet these requirements. There is an alternative; however, to surveys by SAs.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services (the Secretary) as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at §§ 488.4, 488.5 and 488.5(e)(2)(i). The regulations at

§ 488.5(e)(2)(i) require AOs to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

The Joint Commission's current term of approval for their hospital accreditation program expires July 15, 2020.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of a national AO's requirements consider, among other factors, the applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of the Joint Commission's request for continued approval of its hospital accreditation program. This notice also solicits public comment on whether the Joint Commission's requirements meet or exceed the Medicare conditions of participation (CoPs) for hospitals.

III. Evaluation of Deeming Authority Request

The Joint Commission submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its hospital accreditation program. This application was determined to be complete on December 18, 2019. Under section 1865(a)(2) of the Act and our regulations at § 488.5 (Application and re-application procedures for national accrediting organizations), our review and evaluation of the Joint Commission will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of the Joint Commission's standards for hospitals as compared with CMS' hospital CoPs.
- The Joint Commission's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of the Joint Commission's processes to those of state agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ The Joint Commission's processes and procedures for monitoring a hospital found out of compliance with the Joint Commission's program requirements. These monitoring procedures are used only when the Joint Commission identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the SA monitors corrections as specified at § 488.9.

++ The Joint Commission's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ The Joint Commission's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of the Joint Commission's staff and other resources, and its financial viability.

++ The Joint Commission's capacity to adequately fund required surveys.

++ The Joint Commission's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ The Joint Commission's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ The Joint Commission's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Dated: February 6, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2020–03082 Filed 2–14–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0597]

Request for Information on Vaping Products Associated With Lung Injuries

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA) is opening a docket to obtain data and information related to the use of vaping products that are associated with recent lung injuries. This request for information (RFI) responds to direction from Congress to gather information from the public that could help identify and evaluate additional steps the Agency could take to ''address the recent pulmonary illnesses reported to be associated with the use of e-cigarettes and vaping products.'' FDA is seeking information on product design and potential ways to prevent consumers from modifying or adding substances to these products that are not intended by the manufacturers. In particular, FDA is seeking data and information in the form of reports and manuscripts that are unpublished or not available through indexed bibliographic databases. FDA has searched the publicly available scientific literature and is now seeking to supplement that with information not included in the published scientific literature.

DATES: Submit either electronic or written comments or information by April 20, 2020.

ADDRESSES: You may submit either electronic or written comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–0597 for ''Request for Information on Vaping Products Associated With Lung Injuries.'' 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.

• 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.

FOR FURTHER INFORMATION CONTACT: Samantha LohCollado, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, email: *CTPRegulations@fda.hhs.gov,* 1–877–287–1373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the opening of a docket entitled ''Request for Information on Vaping Products Associated With Lung Injuries.''

FDA remains deeply concerned about the recent lung injuries and deaths and is working closely with other agencies, as well as State and local public health partners, to investigate these incidents. To help gather and analyze as much information as possible, FDA is working closely with Federal and State partners to identify the vaping products or other substances that may be causing the injuries. Specifically, FDA is analyzing samples submitted by a number of States for the presence of a broad range of chemicals, including nicotine, tetrahydrocannabinol (THC) and other cannabinoids, along with cutting agents/diluents and other additives, pesticides, opioids, poisons, heavy metals, and toxins. As of February 3, 2020, FDA has received over 1,300 samples from 31 States and 1 territory with roughly 1,070 of these samples connected to patients.[1] These samples have been collected directly from consumers, hospitals, and State offices. They have included vaping devices and products containing varied levels of liquid as well as packaging and other documentation. FDA has not found one product or substance that is implicated in all of the cases; however, we do know that THC is present in most of the samples being tested and many of these samples have vitamin E acetate as a diluent. FDA is following all potential leads and is committed to taking appropriate actions as additional facts emerge.

On December 20, 2019, the President signed the ''Further Consolidated Appropriations Act, 2020'' which directs FDA to issue a RFI to solicit information regarding ''the recent pulmonary illnesses reported to be associated with the use of e-cigarettes and vaping products.''[2] To further this goal, FDA is seeking information related to the use of vaping products that are associated with the recent lung injuries, including public comment on product design and ways to prevent the public from modifying or adding substances to these products that are not intended by the manufacturer. This information may be used by FDA to inform future rulemaking and review of industry premarket application submissions, or in taking other regulatory actions.

II. Request for Information

FDA seeks to obtain data and information related to the use of vaping products that are associated with recent lung injuries. FDA has searched the publicly available scientific literature and is now seeking to supplement that search with information from other sources, specifically unpublished data or other information. If the work is not directly conducted in tobacco products,

[1] For more information regarding FDA's current efforts to identify and address lung injuries related to the use of vaping products, please see *https://www.fda.gov/news-events/public-health-focus/lung-illnesses-associated-use-vaping-products.*

[2] Further Consolidated Appropriations Act, 2020, Public Law 116–94, § 785. FDA uses the term ''vaping products'' for purposes of this RFI. ''Vaping products'' include e-cigarettes as well as other electronic nicotine delivery systems (ENDS). *See* ''Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization,'' available at *https://www.fda.gov/industry/fda-basics-industry/guidances* (defining ''ENDS'' as including ''include devices, components, and/or parts that deliver aerosolized e-liquid when inhaled. For example, FDA considers vapes or vape pens, personal vaporizers, e-cigarettes, cigalikes, e-pens, e-hookahs, e-cigars, and e-pipes to be ENDS.'')

responses should include a discussion of how the information or data can be applied specifically to tobacco products or to lung injuries associated with the use of vaping products.

For this RFI, FDA is requesting: (1) Unpublished data or information (summarized); (2) unpublished or prepublication copies of manuscripts, conference presentations, and/or posters; (3) dissertations and/or theses; and (4) white papers or other unpublished reports. FDA is requesting data and information from all interested parties, including, but not limited to, academic and government researchers, industry, and any other sources.

Specifically, FDA is requesting unpublished data or information on the following:

- Specific chemicals, compounds, ingredients or combinations of ingredients that when inhaled or aerosolized, may be associated with the symptoms observed in ''e-cigarette, or vaping, product use-associated lung injury'' (EVALI) patients; *e.g.,* cough, chest pain, shortness of breath, abdominal pain, nausea, vomiting, diarrhea, fever, chills; [3]
- nature of pulmonary pathological changes associated with inhaling the specific chemicals, compounds, ingredients, or combinations of ingredients that elicit the symptoms observed in EVALI;
- methods or sources for obtaining chemicals, compounds, ingredients, or combinations of ingredients, other than those intended by the manufacturer, that are added to vaping products;
- in what ways and how frequently consumers add chemicals, compounds, ingredients or combinations of ingredients, other than those intended by the manufacturer, to vaping products and how these changes affect the health impacts, frequency, and patterns of consumer use of the products;
- methods for identifying and detecting materials added or modifications to vaping products after the manufacturing process and not intended by the manufacturer; and
- methods of changing the manufacturing process or product design features for vaping products that will reduce or prevent consumers from modifying products after the manufacturing process.

Data may come from studies outside of the United States; however, FDA prefers that reports be submitted in English.

[3] For more information concerning the symptoms observed in EVALI patients, please see *https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease/need-to-know/index.html#symptoms.*

When submitting information, please include details about how the data were collected, including the sample composition, year(s) of data collection, and a detailed summary of the methods and measures used. For data summaries, please include both point estimates and measures of variance, as well as effect sizes (if available).

Please also note that when submitting information and data to the docket, certain compressed file formats (*e.g.,* zip files) are not allowed. Acceptable file formats include: .doc, .docx, .pdf, .ppt, .pptx, .rtf, .txt, .xls, .xlsx, .xlsm, .xlsb, and .wpd.

Dated: February 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03160 Filed 2–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0259]

Patient-Focused Drug Development for Stimulant Use Disorder; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''Patient-Focused Drug Development for Stimulant Use Disorder.'' The purpose of the public meeting is to allow FDA to obtain stakeholder perspectives on the impact of stimulant use disorder and views on treatment approaches for stimulant use disorder.

DATES: The public meeting will be held on March 10, 2020, from 12:30 p.m. to 5 p.m. Submit either electronic or written comments on this public meeting by May 11, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the Silver Spring Civic Building, 1 Veterans Pl., Silver Spring, MD 20910. The building is located at Veterans Plaza in downtown Silver Spring and is accessible via the Silver Spring Metro Station on the Red Line. Paid public parking is also available at the Town Square Garage (Garage 61), 801 Ellsworth Dr., Silver Spring, MD 20910, and the Wayne-Ellsworth Garage (Garage 60), 921 Wayne Ave., Silver Spring, MD 20910. For more information regarding parking, Metro access, and the meeting location, please refer to *https://www.montgomerycountymd.gov/cupf/info-reservation/SSCB.html.*

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 May 11, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 11, 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 No. FDA–2020–N–0259 for ''Patient-Focused Drug Development for Stimulant Use Disorder; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• 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.

FOR FURTHER INFORMATION CONTACT:

Lyna Merzoug, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6308, Silver Spring, MD 20993–0002, 301–796–6001, *PatientFocused@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This meeting will provide FDA the opportunity to obtain input from individuals with stimulant use disorder and other related stakeholders on the impact of stimulant use disorder and views on treatment goals and approaches. FDA is interested in stakeholders' perspectives on: (1) The health effects and daily impacts of their condition; (2) the impact (if any) of opioid and polysubstance use on their condition; (3) treatment goals; and (4) decision factors considered when seeking out or selecting a treatment.

Stimulant use disorder describes a range of problems associated with the use of illicit stimulant drugs, including methamphetamine and cocaine, and prescription stimulants (*e.g.,* ADDERALL, RITALIN), but not including caffeine or nicotine. A diagnosis of stimulant use disorder is made when a clinician identifies a pattern of use of amphetamine-type substance, cocaine, or other stimulant that leads to clinically significant impairment or distress, including an inability to reduce or control consumption, cravings to use a stimulant, continued use of a stimulant despite it causing negative consequences, and the need to use increased amounts of a stimulant to achieve the desired effect. There are no FDA-approved medications for stimulant use disorder.

The questions that will be asked of individuals with stimulant use disorder and other stakeholders at the meeting are listed in the following section and organized by topic. For each topic, a brief initial panel discussion will begin the dialogue. This will be followed by a facilitated discussion inviting comments from other audience participants. In addition to input generated through this public meeting, FDA is interested in receiving stakeholder input addressing these questions through written comments, which can be submitted to the public docket (see **ADDRESSES**). As noted above, when submitting comments, 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.'' When submitting comments, if you are commenting on behalf of a stimulant user, please indicate that you are doing so and answer the following questions as much as possible from the stimulant user's perspective, but please refrain from providing information that would identify third parties, including minor children.

FDA will post the agenda and other meeting materials approximately 5 days before the meeting at *https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-patient-focused-drug-development-stimulant-use-disorder-03102020-03102020.*

II. Discussion Questions at the Public Meeting

A. Topic 1: Health Effects and Daily Impacts

1. How would you describe your experience with stimulant use disorder?

a. Which stimulant(s) did you start using first?

b. What stimulant(s) are you using now?

c. Did you use any other illicit or prescription drugs before you started using the stimulant that you are currently using?

d. How are you using stimulants? How has your stimulant(s) use changed over time? Are you using more frequently or at higher doses?

e. Do you use stimulants in combination with other drug(s)? If so, what other drugs do you use and why?

f. Have you used a stimulant(s) as treatment for opioid withdrawal and/or overdose?

2. Of all the ways that stimulant use disorder impacts your health and well-being, which effects have the most significant impact on your daily life and the daily life of your family and/or friends? Examples may include physical and mental effects of using stimulants (effects on your body and thinking), effects of stimulant withdrawal, effects of cravings, impacts on your ability to function in personal or professional life, or emotional or social effects.

a. What drives your use of stimulants?

b. Are there certain activities that you can only do if you take a stimulant? If so, what are those activities?

c. Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your stimulant use? Examples of activities may include daily hygiene; meeting school, work, or family responsibilities; participation in social activities.

d. How does your stimulant use affect daily life on your best days? On your worst days?

3. What worries you most about your condition?

B. Topic 2: Current Approaches to Management

1. Have you considered seeking treatment? Why or why not?

2. What are you currently doing to help manage your stimulant use?

a. How well have these management approaches worked for you?

b. How well have they helped address the effects of stimulant use that are most troubling to you?

c. What are the biggest problems you have faced in using these approaches? Examples may include bothersome side effects, challenges or barriers to access, concern about stigma.

3. What are the biggest factors that you consider when making decisions about seeking out or engaging in treatment for stimulant use disorder?

4. What specific things would you look for in an ideal treatment for stimulant use disorder?

5. If you had the opportunity to participate in a clinical study to test an experimental treatment for stimulant use disorder, what factors would you consider when deciding whether you would participate?

III. Participating in the Public Meeting

Registration: To register for the public meeting, visit *https://stimulantusedisorder-pfdd.eventbrite.com/.* Contact information provided during registration will remain confidential and only be used to send meeting updates to participants.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by March 3, 2020, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 11:30 a.m.

If you need special accommodations due to a disability, please contact Lyna Merzoug (**SEE FURTHER INFORMATION CONTACT**) no later than March 3, 2020.

Panelist Selection: Stakeholders, particularly people suffering from stimulant use disorder, who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These stakeholders also will be asked to send *PatientFocused@fda.hhs.gov* a brief summary of responses to the discussion questions listed above by February 26, 2020. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Open Public Comment: There will be time allotted during the meeting for open public comment. Signup for this session will be on a first-come, first-serve basis on the day of the workshop. Individuals and organizations with common interests are urged to consolidate or coordinate and request time for a joint presentation. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Persons attending FDA's meetings are advised that FDA is not responsible for providing access to electrical outlets.

Streaming Webcast of the public meeting: FDA will also stream a live audio recording of this public meeting with the presentation slides. The audio recording and presentation slides, along with a meeting transcript and summary report, will also be made publicly available after the meeting. Because of the sensitive nature of the meeting topic, and the importance of gathering candid, meaningful input from individuals who have come forward to speak about living with stimulant use disorder, no other audio recording, video recording, and/or photography will be allowed at this Patient-Focused Drug Development meeting. FDA is asking for your cooperation and strongly requests that you respect the privacy of all attendees. You will be asked to indicate in your registration whether you plan to attend in person or via the webcast. To register for the webcast, please visit *https://stimulantusedisorder-pfdd.eventbrite.com/.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/fda-led-patient-focused-drug-development-pfdd-public-meetings.*

Dated: February 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03159 Filed 2–14–20; 8:45 a.m.]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–E–5899 and FDA–2017–E–5911]

Determination of Regulatory Review Period for Purposes of Patent Extension; INTRAROSA

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 INTRAROSA 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 a patent which claims that human drug product.

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 April 20, 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 August 17, 2020. 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 April 20, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 20, 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–2017–E–5899 and FDA–2017–E–5911 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; INTRAROSA.'' 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.

• 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.

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 human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, 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 human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, INTRAROSA (prasterone), indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause. Subsequent to this approval, the USPTO received patent term restoration applications for INTRAROSA (U.S. Patent Nos. 8,629,129 and 8,957,054) from Endorecherche, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated February 20, 2018, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of INTRAROSA 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 INTRAROSA is 3,381 days. Of this time, 2,983 days occurred during the testing phase of the regulatory review period, while 398 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* August 17, 2007. FDA has verified the applicant's claim that the date the investigational new drug application became effective was August 17, 2007.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* October 16, 2015. FDA has verified the applicant's claim that the new drug application (NDA) for INTRAROSA (NDA 208470) was initially submitted on October 16, 2015.

3. *The date the application was approved:* November 16, 2016. FDA has verified the applicant's claim that NDA 208470 was approved on November 16, 2016.

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 717 days or 518 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: February 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03115 Filed 2–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0019]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before March 19, 2020.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Ed Calimag, *ed.calimag@hhs.gov* or (202) 690–7569. When submitting comments or requesting information, please include the document identifier 4040–0019–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collections: Project Abstract Summary.

Type of Collection: Revision.

OMB No.: 4040–0019.

Abstract: Project Abstract Summary form provides the Federal grant-making agencies an alternative to the Standard Form 424 data set and form. Project Abstract Summary programs are not required to collect all the data that is required on the SF–424 core data set and form. *Grants.gov* seeks revision without renewal and designation as a Common Form due to updates to the IC. The IC was modified to remove data elements. The IC was renewed with an expiration date of 02/28/2022 and does not require an extension.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Project Abstract Summary	3,467	1	1	3,467
Total	3,467			3,467

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2020–03128 Filed 2–14–20; 8:45 am]

BILLING CODE 4151–AE–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting. The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Blood Brain Barrier.

Date: March 19, 2020.

Time: 8:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Michael P. Reilly, Ph.D., Scientific Review Officer, Office of Scientific Review, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7200, Bethesda, MD 20892, 301–827–7975, *reillymp@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases

and Resources Research, National Institutes of Health, HHS)

Dated: February 11, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–03077 Filed 2–14–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; BRAIN Initiative: Novel Tools to Probe Cells and Circuits in the Brain (R01) & Human and NHP Brain (UG3/UH3).

Date: March 11, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street NW, Washington, DC 20036.

Contact Person: Erin E. Gray, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Boulevard, NSC 6152B, Bethesda, MD 20892, 301–402–8152, *erin.gray@nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; BRAIN Initiative: Advanced Human Cell-Based Assays to Model Brain Structure and Function (R01).

Date: March 13, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin Georgetown, 2350 M Street NW, Washington, DC 20037.

Contact Person: David W. Miller, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–9734, *millerda@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; NIMH Clinical Trials Effectiveness Studies (R34/R01/R01 Collaborative).

Date: March 30, 2020.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street NW, Washington, DC 20037.

Contact Person: Karen Gavin-Evans, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 6153, MSC 9606, Bethesda, MD 20892, 301–451–2356, *gavinevanskm@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: February 11, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–03078 Filed 2–14–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cell and Molecular Biology.

Date: March 10–11, 2020.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave. NW, Washington, DC 20037.

Contact Person: Amy Kathleen Wernimont, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6198, Bethesda, MD 20892, (301) 827–6427, *amy.wernimont@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Infectious Diseases, Reproductive Health, Asthma and Pulmonary Conditions: Infectious Disease Epidemiology.

Date: March 13, 2020.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Lisa Steele, Ph.D., Scientific Review Officer, PSE IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 594–6594, *steeleln@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–19–326: Reducing Stigma to Improve HIV/AIDS Prevention, Treatment and Care in Low- and Middle-Income Countries.

Date: March 13, 2020.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Dr., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shalanda A. Bynum, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, Bethesda, MD 20892, (301) 755–4355, *bynumsa@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Dissemination and Implementation Research in Health Review-Overflow.

Date: March 16, 2020.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: John H. Newman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3222, MSC 7808, Bethesda, MD 20892, (301) 435–0628, *newmanjh@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 17–190: Maximizing Investigators' Research Award for Early Stage Investigators (R35).

Date: March 16–17, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Thomas Beres, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 5201, MSC 7840, Bethesda, MD 20892, (301) 435–1175, *berestm@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Oncology.

Date: March 16–17, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Reigh-Yi Lin, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 4152, Bethesda, MD 20892, (301) 827–6009, *lin.reigh-yi@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cancer Diagnostics and Treatments (CDT).

Date: March 16–17, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites—Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Zhang-Zhi Hu, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6186, MSC 7804, Bethesda, MD 20892, (301) 437–8135, *huzhuang@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Gastroenterology.

Date: March 16–17, 2020.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Alexander D. Politis, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3210, MSC 7808, Bethesda, MD 20892, (301) 435–1150, *politisa@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Drug Discovery and Development.

Date: March 16, 2020.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Sergei Ruvinov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, (301) 435–1180, *ruvinser@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Orthopedic, Musculoskeletal, Oral, Skin and Rehabilitation Sciences.

Date: March 16–17, 2020.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Aftab A. Ansari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4108, MSC 7814, Bethesda, MD 20892, (301) 237–9931, *ansaria@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neurodevelopment, Myelination, Transport, and Synaptic Plasticity.

Date: March 16, 2020.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Dr., Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213–9887, *hamelinc@csr.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: February 11, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–03075 Filed 2–14–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; R13 Conference Grants.

Date: March 11, 2020.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Blvd., Rm 1078, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rahat (Rani) Khan, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Blvd., Rm 1078, Bethesda, MD 20892, 301–594–7319, *khanr2@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: February 11, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–03076 Filed 2–14–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2019–0754]

National Maritime Security Advisory Committee; Initial Solicitation for Members

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Request for applications.

SUMMARY: The Coast Guard is requesting applications from persons interested in serving as a member of the National Maritime Security Advisory Committee (''Committee''). This Committee will advise the Secretary of the Department of Homeland Security, via the Commandant of the U.S. Coast Guard, on matters relating to national maritime security, including on enhancing the sharing of information related to cybersecurity risks that may cause a transportation security incident, between relevant Federal agencies and State, local, and tribal governments; relevant public safety and emergency response agencies; relevant law enforcement and security organizations; maritime industry; port owners and operators; and terminal owners and operators. Please read this notice for a description of 21 Committee positions we are seeking to fill.

DATES: Your completed application should reach the Coast Guard on or before April 20, 2020.

ADDRESSES: Applicants should send a cover letter expressing interest in an appointment to the National Maritime Security Advisory Committee and a resume detailing the applicant's experience. We will not accept a biography.

Applications should be submitted via one of the following methods:

- *By Email: ryan.f.owens@uscg.mil* (preferred);
- *By Fax:* 202–372–8428; ATTN: Ryan F. Owens, Alternate Designated Federal Officer; or
- *By Mail:* Mr. Ryan F. Owens, Alternate Designated Federal Officer, Commandant (CG–FAC–1), U.S. Coast Guard Stop 7501, 2703 Martin Luther

King Jr. Avenue SE, Washington, DC 20593–7501.

FOR FURTHER INFORMATION CONTACT: Mr. Ryan Owens, Alternate Designated Federal Officer of the National Maritime Security Advisory Committee; Telephone 202–372–1108; or Email at *ryan.f.owens@uscg.mil.*

SUPPLEMENTARY INFORMATION: The National Maritime Security Advisory Committee is a Federal advisory committee. It will operate under the provisions of the *Federal Advisory Committee Act,* 5 U.S.C., Appendix, the administrative provisions contained in section 601 of the *Frank LoBiondo Coast Guard Authorization Act of 2018 (CGAA18),* Public Law 115–282, 132 Stat. 4192, the *Maritime Transportation Security Act* of *2002* (Pub. L. 107–295, November 25, 2002, as codified in 46 U.S.C. Chapter 701, 46 U.S.C. 70101 *et seq.*), and the provisions of section 15109 of Title 46 of the U.S. Code (46 U.S.C. 15109).

The establishment of the Committee is authorized under *Maritime Transportation Security Act of 2002* as amended by the *Frank LoBiondo Coast Guard Authorization Act of 2018.*

Under 46 U.S.C. 15109, the Committee is to advise the Secretary of Homeland Security on matters relating to national maritime security, including on enhancing the sharing of information related to cybersecurity risks that may cause a transportation security incident, between relevant Federal agencies and—

A. State, local, and tribal governments;

B. relevant public safety and emergency response agencies;

C. relevant law enforcement and security organizations;

D. maritime industry;

E. port owners and operators; and

F. terminal owners and operators.

The Committee is required to hold meetings at least once a year in accordance with 46 U.S.C. 15109(a). We expect the Committee to meet at least twice a year, but it may meet more frequently.

The members listed above are appointed to represent the interests of their respective organizations or associations. They are only considered Special Government Employees, as defined in 18 U.S.C. 202(a), for purposes of (1) 5 U.S.C. 8101–8193; (2) 28 U.S.C. 2671–2680; (3) any other Federal law relating to tort liability; and when they are existing Special Government employees as provided in 46 U.S.C. 15109(e)(2)(B).

The only compensation the members may receive is for travel expenses, including per diem in lieu of subsistence, and/or actual and reasonable expenses incurred in the performance of their direct duties at the Committee.

Under the provisions in 46 U.S.C. 15109(f)(6), if you are appointed as a member of the Committee, your membership term will expire on December 31 of the third full year after the effective date of your appointment. In this initial solicitation for Committee members, we will consider applications for 21 positions:

- Port authorities.
- Facilities owners and operators.
- Terminal owners and operators.
- Vessel owners and operators.
- Maritime labor organizations.
- The academic community.
- State and local governments.
- The maritime industry.

Each member of the Committee must have particular expertise, knowledge, and experience in matters relating to the function of the Committee, which is to advise the Secretary of Homeland Security on the matters described above.

Under 46 U.S.C. 15109(f)(4), its members are required to apply for, obtain, and maintain a government national security clearance at the Secret level. The U.S. Coast Guard will sponsor and assist candidates with this process.

Registered lobbyists are not eligible to serve on Federal Advisory Committees in an individual capacity. See ''*Revised Guidance on Appointment of Lobbyists to Federal Advisory Committees, Boards and Commissions*'' (79 FR 47482, August 13, 2014). Registered lobbyists are ''lobbyists,'' as defined in 2 U.S.C. 1602, who are required by 2 U.S.C. 1603 to register with the Secretary of the Senate and the Clerk of the House of Representatives.

The Department of Homeland Security does not discriminate in selection of Committee members on the basis of race, color, religion, sex, national origin, political affiliation, sexual orientation, gender identity, marital status, disabilities and genetic information, age, membership in an employee organization, or any other non-merit factor. The Department of Homeland Security strives to achieve a widely diverse candidate pool for all of its recruitment selections.

If you are interested in applying to become a member of the Committee, send your cover letter and resume to Mr. Ryan Owens, Alternate Designated Federal Officer of the National Maritime Security Advisory Committee via one of the transmittal methods in the **ADDRESSES** section by the deadline in the **DATES** section of this notice. If you send your application to us via email, we will send you an email confirming receipt of your application.

Dated: January 31, 2020.

David C. Barata,

Captain, U.S. Coast Guard, Director of Inspections and Compliance.

[FR Doc. 2020–03114 Filed 2–14–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2020–0002; Internal Agency Docket No. FEMA–B–2009]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before May 18, 2020.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://www.fema.gov/preliminary floodhazarddata* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS

report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–2009, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://www.fema.gov/preliminaryfloodhazard data* and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Mason County, Michigan (All Jurisdictions) **Project: 13–05–4235S Preliminary Date: August 26, 2019**	
Charter Township of Pere Marquette	Pere Marquette Charter Township Hall, 1699 South Pere Marquette Highway, Ludington, MI 49431.
City of Ludington	City Hall, 400 South Harrison Street, Ludington, MI 49431.
Township of Grant	Grant Township Hall, 843 West Hoague Road, Manistee, MI 49660.
Township of Hamlin	Hamlin Township Hall, 3775 North Jebavy Drive, Ludington, MI 49431.
Township of Summit	Summit Township Hall, 4879 West Deren Road, Ludington, MI 49431.
Oceana County, Michigan (All Jurisdictions) **Project: 13–05–4234S Preliminary Date: August 26, 2019**	
Township of Benona	Benona Township Hall, 7169 West Baker Road, Shelby, MI 49455.
Township of Claybanks	Claybanks Township Hall, 7577 West Cleveland Road, New Era, MI 49446.
Township of Golden	Golden Township Hall, 5527 West Fox Road, Mears, MI 49436.
Township of Pentwater	Township Office, 327 South Hancock Street, Pentwater, MI 49449.
Township of Weare	Weare Township Hall, 6506 North Oceana Drive, Hart, MI 49420.
Village of Pentwater	Village Office, 327 South Hancock Street, Pentwater, MI 49449.
Sanilac County, Michigan (All Jurisdictions) **Project: 14–05–2727S Preliminary Date: September 13, 2019**	
Township of Delaware	Delaware Township Hall, 7979 Maple Grove Road, Minden City, MI 48456.
Township of Forester	Forester Township Hall, 2470 North Lakeshore Road (M–25), Deckerville, MI 48427.
Township of Lexington	Township Hall, 7227 Huron Avenue, Suite 200, Lexington, MI 48450.
Township of Sanilac	Township Hall, 20 North Ridge Street, Port Sanilac, MI 48469.
Township of Worth	Worth Township Hall, 6903 South Lakeshore Road, Lexington, MI 48450.
Village of Forestville	Village Hall, 5605 Cedar Street, Forestville, MI 48434.

Community	Community map repository address
Village of Lexington	Village Hall, 7227 Huron Avenue, Suite 100, Lexington, MI 48450.
Village of Port Sanilac	Village Hall, 56 North Ridge Street, Port Sanilac, MI 48469.

[FR Doc. 2020–03120 Filed 2–14–20; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2020–0002; Internal Agency Docket No. FEMA–B–2011]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before May 18, 2020.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://www.fema.gov/preliminaryfloodhazarddata* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–2011, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://www.fema.gov/preliminaryfloodhazarddata* and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Boulder County, Colorado and Incorporated Areas Project: 19–08–0003S Preliminary Date: September 30, 2019	
City of Boulder	Park Central, 1739 Broadway, Boulder, CO 80302.
City of Longmont	Civic Center, 350 Kimbark Street, Longmont, CO 80501.
Town of Erie	Town Hall, 645 Holbrook Street, Erie, CO 80516.
Town of Jamestown	Town Hall, 118 Main Street, Jamestown, CO 80455.
Town of Lyons	Town Hall, 432 5th Avenue, Lyons, CO 80540.
Town of Nederland	Town Hall, 45 West 1st Street, Nederland, CO 80466.
Town of Superior	Town Hall, 124 East Coal Creek Drive, Superior, CO 80027.
Town of Ward	Town Hall, 1 Columbia Street, Ward, CO 80481.
Unincorporated Areas of Boulder County	Boulder County Transportation Department, 2525 13th Street, Suite 203, Boulder, CO 80304.

[FR Doc. 2020–03121 Filed 2–14–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R7–ES–2019–N138; FF07CAMM00–FX–ES111607MRG01]

Endangered Species; Marine Mammals; Seismic Survey Design and Impacts to Maternal Polar Bear Dens

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability of a peer-reviewed scientific manuscript and associated model; notice of public webinars; and request for public comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce the availability of a peer-reviewed scientific manuscript and associated model regarding seismic survey design and potential impacts to maternal polar bear dens. This manuscript contains information, including a methodology and model that may be used for evaluating the effects of future seismic survey proposals for their potential impacts to maternal polar bear dens. We are also announcing public webinars that will provide an overview of the manuscript and model and respond to questions. We request public comments on the value of the model and the associated methodology described in the peer-viewed scientific manuscript in assisting in the evaluation of the effects of future seismic survey proposals for their potential impacts to maternal polar bear dens.

DATES: Comments will be accepted on or before April 20, 2020.

ADDRESSES: You may obtain a copy of the publication by any of the following methods:

Internet: View or download the document at *https://www.fws.gov/alaska/pages/marine-mammals/polar-bear.*

U.S. mail: Send a request via mail to Marine Mammals Management, U.S. Fish and Wildlife Service, 1011 East Tudor Road, MS 341, Anchorage, Alaska 99503.

Email: Send a request via email to *fw7_ak_marine_mammals@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Marine Mammals Management via the U.S. mail or email address above, by telephone at 1–800–362–5148, or via the Federal Relay Service (FRS) at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), announce the availability of the following peer-reviewed scientific manuscript regarding seismic survey design and impacts to maternal polar bear (Ursus maritimus) dens:

Wilson, R.R. and G.M. Durner. Seismic survey design and impacts to maternal polar bear dens.

This manuscript contains scientific information, including a methodology that may be used for evaluating the effect of future seismic survey proposals for their potential impacts to maternal polar bear dens. Polar bears are currently protected by both the Marine Mammal Protection Act (MMPA; 16 U.S.C. 1361 *et seq.*), and the Endangered Species Act (ESA; 16 U.S.C. 1531 *et seq.*). When evaluating applications for incidental take authorization under the MMPA and when conducting section 7 consultations on proposed Federal actions under the ESA, the Service uses the best available scientific data. Typically, the analysis of a proposed action includes consideration of any overlap between the proposed action and marine mammals and threatened and endangered species, available information on the effects of the proposed action on the species and the species' habitat, and measures to avoid, minimize or mitigate impacts. The scientific methodology and model contained in the manuscript, made available here, is one piece of information being evaluated for use in such an analysis.

It is important to note that the specific analytical approach and inputs for any given analysis will be driven by the proposed action or application submitted to the Service. The referenced manuscript includes a model that was developed to analyze the spatial and temporal overlap between a hypothetical terrestrial seismic survey and denning polar bears. The potential use of this model should be of interest to individuals and entities considering or monitoring activities that may affect polar bears.

We will hold two webinars that will provide an overview of the publication and respond to questions, Thursday, March 19, 2020, from 10:00 a.m. to 11:30 a.m. Alaska Standard Time, and Friday, March 20, 2020, from 10:00 a.m. to 11:30 a.m. Alaska Standard Time. Information on electronically accessing the webinars will be posted on the Service's Alaska Region Marine Mammals Management program website at: *https://www.fws.gov/alaska/pages/marine-mammals.* We request public comments on the value of the methodology and model in the peer-reviewed scientific manuscript to assist in evaluating the effects of seismic survey or other proposals for their potential impacts to maternal polar bear dens.

Dated: February 7, 2020.

Gregory E. Siekaniec,

Regional Director, Alaska Region.

[FR Doc. 2020–03132 Filed 2–14–20; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[20X.LLAZ921000.L14400000.BJ0000. LXSSA2250000.241A]

Notice of Filing of Plat of Survey; Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plat of survey of the following described land was officially filed in the Bureau of Land Management (BLM), Arizona State Office, Phoenix, Arizona, on the date indicated. The survey announced in this notice is necessary for the management of lands administered by the agency indicated.

ADDRESSES: This plat will be available for inspection in the Arizona State Office, Bureau of Land Management, One North Central Avenue, Suite 800, Phoenix, Arizona, 85004–4427. Protests of the survey should be sent to the Arizona State Director at the above address.

FOR FURTHER INFORMATION CONTACT: Geoffrey Graham, Chief Cadastral Surveyor of Arizona; (602) 417–9558; *ggraham@blm.gov*. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

The Gila and Salt River Meridian, Arizona

The supplemental plat, in three sheets, showing the segregation of Public Land Order No. 5132 from Tract 48, Township 1 South, Range 13 East, accepted February 11, 2020, and officially filed February 13, 2020, for Group 9117, Arizona.

This plat was prepared at the request of the Bureau of Land Management.

A person or party who wishes to protest against this survey must file a written notice of protest within 30 calendar days from the date of this publication with the Arizona State Director, Bureau of Land Management, stating that they wish to protest.

A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within 30 days after the protest is filed. Before including your address, or other personal information in your protest, please be aware that your entire protest, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 43 U.S.C. Chap. 3.)

Geoffrey A. Graham,

Chief Cadastral Surveyor of Arizona.

[FR Doc. 2020–03130 Filed 2–14–20; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[20X.LLIDB00000.L16100000.DP0000. LXSS053D0000.241A.4500141729]

Notice of Availability of the Proposed Four Rivers Field Office Resource Management Plan and Final Environmental Impact Statement, Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) has prepared a Proposed Resource Management Plan (RMP) and Final Environmental Impact Statement (EIS) for the Four Rivers Field Office (FRFO) and by this notice is announcing its availability.

DATES: Persons or groups with standing to protest the Proposed RMP and Final EIS must submit protests in writing within 30 days of the date that the Environmental Protection Agency publishes its Notice of Availability in the **Federal Register**.

ADDRESSES: The Proposed RMP and Final EIS are available on the BLM ePlanning project website at *http://go.usa.gov/xnsn6* (case sensitive). Click the ''Documents and Report'' link on the left side of the screen to find the electronic version of these materials. Hard copies of the Proposed RMP/Final EIS are also available for public inspection at the Idaho State Office, 1387 South Vinnell Way, Boise ID 83709 and the Boise District Office, 3948 Development Ave., Boise ID 83705.

All protests must be in writing and filed with the BLM Director, either as a hard copy or electronically via the BLM's ePlanning project website listed previously. To submit a protest electronically, go to the ePlanning project website and follow the protest instructions highlighted at the top of the home page. If submitting a protest in hard copy, it must be mailed to one of the following addresses:

Regular Mail: BLM Director (210), Attention: Protest Coordinator, P.O. Box 71383, Washington, D.C. 20024–1383

Overnight Delivery: BLM Director (210), Attention: Protest Coordinator, Attention: Protest Coordinator, 20 M Street SE., Room 2134LM, Washington, D.C. 20003

FOR FURTHER INFORMATION CONTACT: Brent Ralston, Field Manager; telephone 208–384–3300; address 3948 Development Ave, Boise, ID 83705; email *Four_Rivers_RMP@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact Mr. Ralston during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The FRFO encompasses an area in southwestern Idaho extending north of the Snake River from approximately Glenns Ferry in the southeast, west to Weiser, and north to McCall. The planning area includes all public lands within the FRFO located outside of the the Morley Nelson Snake River Birds of Prey National Conservation Area (NCA), which is governed by a separate RMP. The Four Rivers RMP will determine management for approximately 783,000 surface acres and 1,173,150 acres of mineral estate in Ada, Adams, Boise, Camas, Canyon, Elmore, Gem, Owyhee, Payette, Valley, and Washington counties administered by the BLM. Much of the planning area comprises interspersed sections of public, private, State or U.S. Forest Service lands. When approved, the Four Rivers RMP will replace the 1983 Kuna Management Framework Plan, the 1987 Jarbidge RMP, and the 1988 Cascade RMP.

The BLM engaged in public scoping to help identify planning issues that directed the formulation of alternatives and framed the analysis. Issues include managing the scattered BLM-administered land base, balancing increasing public demand with conservation of resources, and balancing resource uses (including energy development). The planning effort also considers socio-economic concerns and special designations including lands

with wilderness characteristics, wild and scenic rivers and Areas of Critical Environmental Concern (ACECs).

The Draft RMP/Draft EIS evaluated four alternatives in detail. Alternative A, the No Action Alternative, continues current management in the existing Land Use Plans (LUP). It does not address issues that were nonexistent or unforeseen when the BLM prepared the original LUPs.

Alternative B protects natural resource values from potential impacts of population growth and increased use and incorporates protective measures for plants and wildlife compared to other alternatives. While some areas emphasize recreation and community development uses, the primary emphases are for conservation and reduction of habitat fragmentation and resource degradation.

Alternative C accommodates increased population growth and use of public lands by emphasizing land disposal for local community expansion, providing economic expansion through extractive and renewable energy resource development and continues to provide recreational opportunities.

Alternative D, the Preferred Alternative in the Draft RMP/Draft EIS, is the Proposed Plan in the Final EIS and emphasizes management of public lands to promote economic development while maintaining natural resource values. The Proposed RMP opens some areas to fluid mineral development, improves opportunities to manage or reduce invasive annual grasses, maintains three ACECs, and improves opportunities for access to public lands. The FRFO Draft RMP/Draft EIS public comment period began on May 24, 2019, and was extended for 30 days at the request of the State of Idaho to September 23, 2019. The BLM conducted four public open house meetings during the public comment period. The BLM considered and incorporated, as appropriate, comments on the Draft RMP/Draft EIS received from the public, State of Idaho, other cooperating agencies and internal BLM review. Public comments resulted in the addition of management actions and clarifying text and the retention of the Boise Front ACEC. These changes do not significantly change the proposed LUP decisions.

Instructions for filing a protest with the Director of the BLM regarding the Proposed RMP and Final EIS may be found online at *https://www.blm.gov/programs/planning-and-nepa/public-participation/filing-a-plan-protest* and at 43 CFR 1610.5–2. All protests must be in writing and mailed to the appropriate address, as set forth in the **ADDRESSES** section or submitted electronically through the BLM ePlanning project website as described above. Protests submitted electronically by any means other than the ePlanning project website protest section will be invalid unless a protest is also submitted in hard copy. Protests submitted by fax will also be invalid unless also submitted either through ePlanning project website protest section or in hard copy.

Before including your phone number, email address, or other personal identifying information in your protest, you should be aware that your entire protest—including your personal identifying information—may be made publicly available at any time. While you can ask us in your protest to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2, 43 CFR 1610.5)

John F. Ruhs,

Idaho BLM State Director.

[FR Doc. 2020–03035 Filed 2–14–20; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[19X.LLID930000.L11700000.DF0000. LXSGPL000000.241A.4500132602]

Notice of Availability of the Final Programmatic Environmental Impact Statement for Fuel Breaks in the Great Basin; Idaho, Washington, Oregon, California, Nevada and Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, the Bureau of Land Management (BLM) has prepared a Final Programmatic Environmental Impact Statement (EIS) for Fuel Breaks in the Great Basin and by this notice is announcing its availability.

DATES: The BLM will not issue a final decision on the proposal for a minimum of 30 days after the date that the Environmental Protection Agency publishes its Notice of Availability (NOA) in the **Federal Register**.

ADDRESSES: Copies of the Final Programmatic EIS for Fuel Breaks in the Great Basin are available for public inspection during regular business hours at 1387 South Vinnell Way, Boise ID 83709. Interested persons may also review the Final Programmatic EIS online at: *https://go.usa.gov/xnQcG*. Additional copies can be made available at the California, Nevada, Oregon/Washington and Utah BLM State Offices upon request.

FOR FURTHER INFORMATION CONTACT: Ammon Wilhelm, telephone 208–373–3824; address BLM Idaho State Office, 1387 South Vinnell Way, Boise ID 83709; email *awilhelm@blm.gov* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Strategically placed fuel breaks in the Great Basin region would improve firefighter safety and expand opportunities to catch rapidly moving fires, potentially reducing fire size. Fuel breaks should provide greater protection of human life and property, sagebrush communities, and habitat restoration investments. Reducing fire size helps to reduce the expansion of invasive species, such as cheatgrass and medusahead. Fuel breaks are needed due to the increased size and frequency of wildfires throughout the western United States in recent years. From 2009 through 2018 over 13.5 million acres of BLM-administered lands burned within the project area, impacting healthy rangelands, sagebrush communities, and the general productivity of the lands. Larger and more frequent wildfires result in increased risk for injuries and fatalities among wildland firefighters, destruction of private property, degradation and loss of rangelands, loss of recreational opportunities, and habitat loss for a variety of species, including conversion of native habitats to invasive annual grasses. Conversion of rangeland habitats to invasive annual grasslands further impedes rangeland health and productivity by slowing or preventing the recovery of sagebrush ecosystems.

This programmatic environmental impact statement (EIS) evaluates the Bureau of Land Management (BLM) proposal to create and maintain a system of fuel breaks in the Great Basin region. The project area, covering nearly 224 million acres, includes portions of California, Idaho, Nevada, Oregon, Utah, and Washington. The fuel breaks would be placed along a subset of available linear features, such as roads and rights-of-way on BLM-administered lands within sagebrush communities; these

potential treatment areas cover approximately 38 million acres within the project area boundary. The preferred alternative (Alternative D) analyzes a full suite of manual, chemical and mechanical treatments, including prescribed fire, seeding, and targeted grazing, to construct and maintain up to 11,000 miles of fuel breaks, potentially removing or altering vegetation on approximately 667,000 acres and protecting approximately 38 million acres of the sagebrush ecosystem. Fuel break types include green strips (areas planted with low-statured, fire-resistant vegetation), brown strips (areas where all vegetation is removed), and mowed fuel breaks (reduced vegetation height).

The NOA for the Draft Programmatic EIS published on June 21, 2019, initiating a 45-day public comment period. During July 2019, the BLM hosted 12 public comment meetings throughout the six-state project area. Agencies, organizations, and interested parties provided comments on the draft Programmatic EIS via mail, email, and at the public meetings. The BLM received 907 comment form letters and 138 unique comment letters. Comments on the Draft Programmatic EIS received from the public and internal BLM review were considered and incorporated as appropriate into the Final Programmatic EIS. Public comments resulted in the addition of clarifying text, but did not significantly change the alternatives or analysis.

Authority: 40 CFR 1506.6, 40 CFR 1506.10.

John F. Ruhs,

Idaho State Director, Bureau of Land Management.

[FR Doc. 2020–03163 Filed 2–14–20; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

[Docket ID BSEE–2019–0013; 201E1700D2 ET1SF0000.EAQ000 EEEE500000; OMB Control Number 1014–0026]

Agency Information Collection Activities; Application for Permit To Modify (APM) and Supporting Documentation

AGENCY: Bureau of Safety and Environmental Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Safety and Environmental Enforcement (BSEE) proposes to renew an information collection.

DATES: Interested persons are invited to submit comments on or before April 20, 2020.

ADDRESSES: Send your comments on this information collection request (ICR) by either of the following methods listed below:

- Electronically go to *http://www.regulations.gov.* In the Search box, enter BSEE–2019–0013 then click search. Follow the instructions to submit public comments and view all related materials. We will post all comments.
- Email *kye.mason@bsee.gov,* fax (703) 787–1546, or mail or hand-carry comments to the Department of the Interior; Bureau of Safety and Environmental Enforcement; Regulations and Standards Branch; ATTN: Nicole Mason; 45600 Woodland Road, Sterling, VA 20166. Please reference OMB Control Number 1014–0026 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Nicole Mason by email at *kye.mason@bsee.gov* or by telephone at (703) 787–1607.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comments addressing the following issues: (1) Is the collection necessary to the proper functions of BSEE; (2) Will this information be processed and used in a timely manner; (3) Is the estimate of burden accurate; (4) How might BSEE enhance the quality, utility, and clarity of the information to be collected; and (5) How might BSEE minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you 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.

Abstract: Throughout the regulations at 30 CFR part 250, BSEE requires the submission of Applications for Permit to Modify, and all supporting documentation on form BSEE–0124 that pertain to regulatory requirements of oil, gas, and sulfur operations in the Outer Continental Shelf (OCS) (including the associated forms), and are the subject of this collection. This request also covers any related Notices to Lessees and Operators (NTLs) that BSEE issues to clarify, supplement, or provide additional guidance on some aspects of our regulations.

The BSEE uses the information to ensure safe well control, completion, workover, and decommissioning operations and to protect the human, marine, and coastal environment. Among other things, BSEE specifically uses the information (see the burden table under A.12 to see what specific information BSEE collects) to ensure: The well control, completion, workover, and decommissioning unit (drilling/well operations) is fit for the intended purpose; equipment is maintained in a state of readiness and meets safety standards; each drilling/well operation crew is properly trained and able to promptly perform well-control activities at any time during well operations; compliance with safety standards; and the current regulations will provide for safe and proper field or reservoir development, resource evaluation, conservation, protection of correlative rights, safety, and environmental protection. We also review well records to ascertain whether the operations have encountered hydrocarbons or H2S and to ensure that H2S detection equipment, personnel protective equipment, and training of the crew are adequate for safe operations in zones known to contain H2S and zones where the presence of H2S is unknown.

Title of Collection: 30 CFR part 250, Application for Permit to Modify (APM) and supporting documentation.

OMB Control Number: 1014–0026.

Form Number: BSEE–0124.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Potential respondents are comprised of Federal OCS oil, gas, and sulfur lessees/

operators and holders of pipeline rights-of-way.

Total Estimated Number of Annual Respondents: Not all the potential respondents will submit information at any given time, and some may submit multiple times.

Total Estimated Number of Annual Responses: 12,252.

Estimated Completion Time per Response: Varies from 10 minutes to 154 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 17,353.

Respondent's Obligation: Responses are mandatory.

Frequency of Collection: On occasion and varies by section.

Total Estimated Annual Nonhour Burden Cost: $6,446,500.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

Amy White,

Acting Chief, Regulations and Standards Branch.

[FR Doc. 2020–03131 Filed 2–14–20; 8:45 am]

BILLING CODE 4310–VH–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Nicotine Pouches and Components Thereof and Methods of Making the Same DN 3434;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of NYZ AB, Swedish Match North America, LLC, Pinkerton Tobacco Co., LP; and wm17 holding GmbH on February 10, 2020. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain nicotine pouches and components thereof and methods of making the same. The complaint names as respondents: The Art Factory AB of Sweden; Kretek International, Inc. of Moorpark, CA; and DRYFT Sciences, LLC of Moorpark, CA. The complainant requests that the Commission issue a limited exclusion and cease desist orders and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to § 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 3434'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures).[1] Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: February 11, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–03085 Filed 2–14–20; 8:45 am]

BILLING CODE 7020–02–P

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–20–0003; NARA–2020–020]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice of certain Federal agency requests for records disposition authority (records schedules). We publish notice in the **Federal Register** and on *regulations.gov* for records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on such records schedules.

DATES: NARA must receive comments by April 3, 2020.

ADDRESSES: You may submit comments by either of the following methods. You must cite the control number, which appears on the records schedule in parentheses after the name of the agency that submitted the schedule.

- *Federal eRulemaking Portal: http://www.regulations.gov.*
- *Mail:* Records Appraisal and Agency Assistance (ACR); National Archives and Records Administration; 8601 Adelphi Road, College Park, MD 20740–6001.

FOR FURTHER INFORMATION CONTACT: Kimberly Keravuori, Regulatory and External Policy Program Manager, about this notice by email at *regulation_comments@nara.gov.* For information on the schedules, contact Records Management Operations by email at *request.schedule@nara.gov,* by mail at the address above, or by phone at 301–837–1799.

SUPPLEMENTARY INFORMATION:

Public Comment Procedures

We are publishing notice of records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on these records schedules, as required by 44 U.S.C. 3303a(a), and list the schedules at the end of this notice by agency and subdivision requesting disposition authority.

In addition, this notice lists the organizational unit(s) accumulating the records or states that the schedule has agency-wide applicability. It also provides the control number assigned to each schedule, which you will need if you submit comments on that schedule.

We have uploaded the records schedules and accompanying appraisal memoranda to the regulations.gov docket for this notice as ''other'' documents. Each records schedule contains a full description of the records at the file unit level as well as their proposed disposition. The appraisal memorandum for the schedule includes information about the records.

We will post comments, including any personal information and attachments, to the public docket unchanged. Because comments are public, you are responsible for ensuring that you do not include any confidential or other information that you or a third party may not wish to be publicly posted. If you want to submit a comment with confidential information or cannot otherwise use the *regulations.gov* portal, you may contact *request.schedule@nara.gov* for instructions on submitting your comment.

We will consider all comments submitted by the posted deadline and consult as needed with the Federal agency seeking the disposition authority. After considering comments, we will post on *regulations.gov* a ''Consolidated Reply'' summarizing the comments, responding to them, and noting any changes we have made to the proposed records schedule. We will then send the schedule for final approval by the Archivist of the United States. You may elect at *regulations.gov* to receive updates on the docket, including an alert when we post the Consolidated Reply, whether or not you submit a comment. If you have a question, you can submit it as a comment, and can also submit any concerns or comments you would have to a possible response to the question. We will address these items in consolidated replies along with any other comments submitted on that schedule.

We will post schedules on our website in the Records Control Schedule (RCS) Repository, at *https://www.archives.gov/records-mgmt/rcs,* after the Archivist approves them. The RCS contains all schedules approved since 1973.

Background

Each year, Federal agencies create billions of records. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval. Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. The records schedules authorize agencies to preserve records of continuing value in the National Archives or to destroy, after a specified period, records lacking continuing administrative, legal, research, or other value. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

Agencies may not destroy Federal records without the approval of the Archivist of the United States. The Archivist grants this approval only after thorough consideration of the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the

Government's activities, and whether or not the records have historical or other value. Public review and comment on these records schedules is part of the Archivist's consideration process.

Schedules Pending

1. Department of Defense, Defense Counterintelligence and Security Agency, Continuous Evaluation Information System (DAA–0446–2019–0007).
2. National Archives and Records Administration, Research Services, General Records of the Department of State (N2–059–19–001).
3. Office of Personnel Management, Agency-wide, Records of the Office of the Director (DAA–0478–2017–0002).

Laurence Brewer,

Chief Records Officer for the U.S. Government.

[FR Doc. 2020–03158 Filed 2–14–20; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Humanities

Meeting of Humanities Panel

AGENCY: National Endowment for the Humanities; National Foundation on the Arts and the Humanities.

ACTION: Notice of meeting.

SUMMARY: The National Endowment for the Humanities will hold twelve meetings of the Humanities Panel, a federal advisory committee, during March 2020. The purpose of the meetings is for panel review, discussion, evaluation, and recommendation of applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965.

DATES: See **SUPPLEMENTARY INFORMATION** for meeting dates. The meetings will open at 8:30 a.m. and will adjourn by 5:00 p.m. on the dates specified below.

ADDRESSES: The meetings will be held at Constitution Center, 400 7th Street SW, Washington, DC 20506, unless otherwise indicated.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Committee Management Officer, 400 7th Street SW, Room 4060, Washington, DC 20506; (202) 606–8322; *evoyatzis@neh.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App.), notice is hereby given of the following meetings:

1. Date: March 11, 2020

This meeting will discuss applications on the topics of American History and Literature, for the Scholarly Editions and Translations grant program, submitted to the Division of Research Programs.

2. Date: March 12, 2020

This meeting will discuss applications on the topics of History and Studies of the Americas, for the Collaborative Research grant program, submitted to the Division of Research Programs.

3. Date: March 23, 2020

This meeting will discuss applications on the topics of History and Literature, for the Scholarly Editions and Translations grant program, submitted to the Division of Research Programs.

4. Date: March 23, 2020

This meeting will discuss applications for the Public Humanities Projects: Historic Places (Implementation) grant program, submitted to the Division of Public Programs.

5. Date: March 24, 2020

This meeting will discuss applications on the topic of U.S. History, for the Public Humanities Projects: Exhibitions (Implementation) grant program, submitted to the Division of Public Programs.

6. Date: March 24, 2020

This meeting will discuss applications for the National Digital Newspaper Program, submitted to the Division of Preservation and Access.

7. Date: March 25, 2020

This meeting will discuss applications on the topics of Literature and the Arts, for the Collaborative Research grant program, submitted to the Division of Research Programs.

8. Date: March 26, 2020

This meeting will discuss applications on the topics of Literature and the Arts, for the Collaborative Research grant program, submitted to the Division of Research Programs.

9. Date: March 26, 2020

This meeting will discuss applications on the topic of Cultural History, for Media Projects: Production Grants, submitted to the Division of Public Programs.

10. Date: March 27, 2020

This meeting will discuss applications on the topic of Place-Based History, for the Public Humanities Projects: Exhibitions (Implementation) grant program, submitted to the Division of Public Programs.

11. Date: March 31, 2020

This meeting will discuss applications for the Short Documentaries grant program, submitted to the Division of Public Programs.

12. Date: March 31, 2020

This meeting will discuss applications for Landmarks of American History and Culture Workshops, submitted to the Division of Education Programs.

Because these meetings will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, the meetings will be closed to the public pursuant to sections 552b(c)(4) and 552b(c)(6) of Title 5, U.S.C., as amended. I have made this determination pursuant to the authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings dated April 15, 2016.

Dated: February 11, 2020.

Elizabeth Voyatzis,

Committee Management Officer, National Endowment for the Humanities.

[FR Doc. 2020–03080 Filed 2–14–20; 8:45 am]

BILLING CODE 7536–01–P

NATIONAL SCIENCE FOUNDATION

Request for Information—Partnerships in Ocean Science and Technology

AGENCY: National Science Foundation.

ACTION: Notice of Request for Information on opportunities and constraints to building and sustaining partnerships in ocean science and technology.

SUMMARY: The National Science Foundation (NSF), on behalf of the Office of Science and Technology Policy (OSTP), requests input from all interested parties on opportunities for and constraints on building and sustaining partnerships in ocean science and technology (S&T). The public input provided in response to this Request for Information (RFI) will inform OSTP as it works with the Council on Environmental Quality (CEQ), Federal agencies, and other stakeholders to identify opportunities to build and sustain partnerships in ocean science and technology.

DATES: Interested persons are invited to submit comments on or before March 19, 2020.

ADDRESSES: Responses should be submitted via email to *oceansummit@ostp.eop.gov.* Include ''Partnerships in Ocean Science and Technology'' in the subject line of the message.

Instructions: Response to this RFI is voluntary. Respondents need not reply to all questions listed. For submissions via email, clearly indicate which questions are being answered. Email attachments will be accepted in plain text, Microsoft Word, or Adobe PDF formats only. Each individual or institution is requested to submit only one response. OSTP may post responses to this RFI, without change, on a Federal website. OSTP, therefore, requests that no business proprietary information, copyrighted information, or personally identifiable information be submitted in response to this RFI. Please note that the U.S. Government will not pay for response preparation, or for the use of any information contained in the response.

FOR FURTHER INFORMATION CONTACT: Deerin Babb-Brott, OSTP, *Deerin_S_Babb-Brott2@ostp.eop.gov,* 202–456–4444.

SUPPLEMENTARY INFORMATION: In 2018, the Trump Administration issued Science and Technology for America's Oceans: A Decadal Vision (Decadal Vision), which identified five goals to advance U.S. ocean S&T in the coming decade, including: (1) Understand the ocean in the earth system; (2) promote economic prosperity; (3) ensure maritime security; (4) safeguard human health; and (5) develop resilient coastal communities. The Decadal Vision also described areas of immediate ocean research and technology opportunities, including (1) fully integrating Big Data approaches in Earth system science; (2) advancing monitoring and predictive modeling capabilities; (3) improving data integration in decision-support tools; (4) supporting ocean exploration and characterization; and (5) supporting ongoing research and technology partnerships.

On November 14, 2019, OSTP and CEQ hosted The White House Summit on Partnerships in Ocean Science and Technology (Ocean S&T Summit). The Ocean S&T Summit brought together over 100 leaders and experts from philanthropy, the private sector, academia, and the Federal government to identify opportunities for S&T partnerships that advance the goals framed by the Decadal Vision. The Ocean S&T Summit addressed the following specific themes: (1) Exploring the Ocean; (2) Conserving Marine Living Resources; (3) Protecting Coastal Health and Safety; (4) Sustaining Ocean Observations; (5) Promoting Food Security; (6) Enabling Ocean Energy; (7) Characterizing Ocean Life; and (8) Leveraging Big Data. A summary of the Ocean S&T Summit is available at: *https://www.whitehouse.gov/wp-content/uploads/2019/11/Ocean-ST-Summit-Readout-Final.pdf.*

OSTP is soliciting public input through this RFI to obtain information from a wide range of stakeholders, including academia, private sector, philanthropy, and other relevant organizations and institutions, in order to inform OSTP and CEQ as they prepare to identify these opportunities and develop recommendations for collaboration across the ocean S&T enterprise.

Questions To Inform Development of the Recommendations

Through this RFI, OSTP seeks responses to the following questions to identify opportunities and inform development of recommendations that will address opportunities and barriers to partnerships in ocean science and technology across and among academia, private industry, philanthropy, and government sectors.

1. Please describe opportunities for cross-sector partnerships and collaborations in ocean S&T where the Federal government's participation or facilitation could advance the development and application of ocean S&T. The term ''partnership'' is defined broadly to include all Federal mechanisms available to engage, collaborate, and exchange resources, among other activities, with non-Federal organizations.

2. Please identify existing effective cross-sector partnerships in ocean S&T and the characteristics that cause them to be successful. Please specify what kinds of institutions (including the Federal government) are involved and describe their roles.

3. Please describe opportunities for the Federal government to strengthen or facilitate existing ocean S&T partnerships in the private, nonprofit, and other sectors. In what specific types of partnerships should they play a larger role and why?

4. Executive Order 13840, titled, *Ocean Policy to Advance the Economic, Security, and Environmental Interests of the United States,* highlights and supports Federal participation in projects conducted under the National Oceanographic Partnership Program (*www.nopp.org*) to maximize the effectiveness of agency investments in ocean research. Please describe opportunities to enhance utilization of the program by both Federal agencies and non-Federal partners.

5. Please describe existing barriers or constraints that limit opportunities for cross-sector partnerships in ocean S&T, including barriers limiting partnerships with the Federal government. Barriers or constraints may include legal authorities, regulatory, policy, cultural, lack of expertise, or other procedural hurdles that limit or prevent partnership opportunities.

Dated: February 11, 2020.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2020–03071 Filed 2–14–20; 8:45 am]

BILLING CODE 7555–01–P

POSTAL SERVICE

Board of Governors; Sunshine Act Meeting

TIME AND DATE: February 7, 2020, at 8:00 a.m.

PLACE: Washington, DC

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Administrative Matters.
2. Strategic Matters.

On February 7, 2020, a majority of the members of the Board of Governors of the United States Postal Service voted unanimously to hold and to close to public observation a special meeting in Washington, DC. The Board determined that no earlier public notice was practicable.

General Counsel Certification: The General Counsel of the United States Postal Service has certified that the meeting may be closed under the Government in the Sunshine Act.

CONTACT PERSON FOR MORE INFORMATION: Michael J. Elston, Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza SW, Washington, DC 20260–1000. Telephone: (202) 268–4800.

Michael J. Elston,

Secretary.

[FR Doc. 2020–03254 Filed 2–13–20; 4:15 pm]

BILLING CODE 7710–12–P

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

Summary: In accordance with the requirement of Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public

comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

1. Title and purpose of information collection: Placement Service; OMB 3220–0057. Section 12(i) of the Railroad Unemployment Insurance Act (RUIA), authorizes the RRB to establish, maintain, and operate free employment offices to provide claimants for unemployment benefits with job placement opportunities. Section 704(d) of the Regional Railroad Reorganization Act of 1973, as amended, and as extended by the Consolidated Omnibus Budget Reconciliation Act of 1985, required the RRB to maintain and distribute a list of railroad job vacancies, by class and craft, based on information furnished by rail carriers to the RRB. Although the requirement under the law expired effective August 13, 1987, the RRB has continued to obtain this information in keeping with its employment service responsibilities under Section 12(k) of the RUIA. Application procedures for the job placement program are prescribed in 20 CFR 325. The procedures pertaining to the RRB's obtaining and distributing job vacancy reports furnished by rail carriers are described in 20 CFR 346.1.

The RRB currently utilizes four forms to obtain information needed to carry out its job placement responsibilities. Form ES–2, *Central Register Notification,* is used by the RRB to obtain information needed to update a computerized central register of separated and furloughed railroad employees available for employment in the railroad industry. Forms ES–21, *Referral to State Employment Service,* and ES–21c, *Report of State Employment Service Office,* are used by the RRB to provide placement assistance for unemployed railroad employees through arrangements with State Employment Service offices. Form UI–35, Field Office Record of Claimant Interview, is used primarily by the RRB to conduct in-person interviews of claimants for unemployment benefits.

Completion of these forms is required to obtain or maintain a benefit. In addition, the RRB also collects Railroad Job Vacancies information received voluntarily from railroad employers. The RRB no longer offers the Central Register as a basic employment service as of April 2017 and propose to obsolete Form ES–2. The RRB proposes no changes to Forms ES–21 and ES–21c and proposes minor changes to Form UI–35 to remove all reference to the obsolete Central Register and renumber accordingly.

ESTIMATE OF CURRENT ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
ES–2	3,750	0.25	16
ES–21	80	0.68	0.9
ES–21c	25	1.50	0.6
* UI–35 in person	6,300	7.00	735
* UI–35 by mail	700	10.50	123
Job Vacancies	470	10.00	78
Total	11,325	.....	953

ESTIMATE OF PROPOSED ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
ES–21	80	1.00	1
ES–21c	25	2.00	1
*UI–35 in person	6,300	7.00	735
*UI–35 by mail	700	11.00	128
Job Vacancies	470	10.00	78
Total	7,575	.....	943

2. Title and purpose of information collection: Certification Regarding Rights to Unemployment Benefits; OMB 3220–0079.

Under Section 4 of the Railroad Unemployment Insurance Act (RUIA), an employee who leaves work voluntarily is disqualified for unemployment benefits unless the employee left work for good cause and is not qualified for unemployment benefits under any other law. RRB Form UI–45, *Claimant's Statement—Voluntary Leaving of Work,* is used by the RRB to obtain the claimant's statement when the claimant, the claimant's employer, or another source indicates that the claimant has voluntarily left work.

Completion of Form UI–45 is required to obtain or retain benefits. One response is received from each respondent. The RRB proposes no changes to Form UI–45.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
UI–45	200	15	50
Total	200		50

3. Title and purpose of information collection: Self-Employment and Substantial Service Questionnaire; OMB 3220–0138.

Section 2 of the Railroad Retirement Act (RRA) provides for payment of annuities to qualified employees and their spouses. In order to receive an age and service annuity, Section 2(e)(3) states that an applicant must stop all railroad work and give up any rights to return to such work. However, applicants are not required to stop nonrailroad work or self-employment.

The RRB considers some work claimed as ''self-employment'' to actually be employment for an employer. Whether the RRB classifies a particular activity as self-employment or as work for an employer depends upon the circumstances of each case. These circumstances are prescribed in 20 CFR 216.

Under the 1988 amendments to the RRA, an applicant is no longer required to stop work for a ''Last Pre-Retirement Nonrailroad Employer'' (LPE). However, Section 2(f)(6) of the RRA requires that a portion of the employee's Tier II benefit and supplemental annuity be deducted for earnings from the ''LPE.''

The ''LPE'' is defined as the last person, company, or institution with whom the employee or spouse applicant was employed concurrently with, or after, the applicant's last railroad employment and before their annuity beginning date. If a spouse never worked for a railroad, the LPE is the last person for whom he or she worked.

The RRB utilizes Form AA–4, *Self-Employment and Substantial Service Questionnaire,* to obtain information needed to determine if the work the applicant claims is self-employment is really self-employment or work for an LPE or railroad service. If the work is self-employment, the questionnaire identifies any month in which the applicant did not perform substantial service. One response is requested of each respondent. Completion is voluntary. However, failure to complete the form could result in the nonpayment of benefits. The RRB proposes to the following changes to Form AA–4:

- Update the officer title and RRB zip code in the Paperwork Reduction Act/Privacy Act Notices section;
- update the example date in Section 1—General Instructions; and
- update the RRB office hours in Section 7—Certification.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
AA–4 (With assistance)	570	40	380
AA–4 (Without assistance)	30	70	35
Total	600		415

4. Title and purpose of information collection: Withholding Certificate for Railroad Retirement Monthly Annuity Payments; OMB 3220–0149.

The Internal Revenue Code requires that all payers of tax liable private pensions to U.S. citizens or residents: (1) Notify each recipient at least concurrent with initial withholding that the payer is, in fact, withholding benefits for tax liability and that the recipient has the option of electing not to have the payer withhold, or to withhold at a specific rate; (2) withhold benefits for tax purposes (in the absence of the recipient's election not to withhold benefits); and (3) notify all beneficiaries, at least annually, that they have the option to change their withholding status or elect not to have benefits withheld.

The RRB provides Form RRB–W4P, Withholding Certificate for Railroad Retirement Payments, to its annuitants to exercise their withholding options. Completion of the form is required to obtain or retain a benefit. One response is requested of each respondent. The RRB proposes no changes to Form W–4P.

The RRB estimates that 25,000 annuitants utilize Form RRB W–4P annually. The completion time for Form RRB W–4P varies depending on individual circumstances. The estimated average completion time for Form RRB W–4P is 39 minutes for recordkeeping, 24 minutes for learning about the law or the form, and 59 minutes for preparing the form.

5. Title and purpose of information collection: Designation of Contact Officials; 3220–0200 Coordination between railroad employers and the RRB is essential to properly administer the payment of benefits under the Railroad Retirement Act (RRA) and the Railroad Unemployment Insurance Act (RUIA). In order to enhance timely coordination activity, the RRB utilizes Form G–117a, *Designation of Contact Officials.* Form G–117a is used by railroad employers to designate employees who are to act as point of contact with the RRB on a variety of RRA and RUIA-related matters.

Completion is voluntary. One response is requested from each respondent. The RRB proposes no changes to Form G–117a.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
G–117a	100	15	25
Total	100		25

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, contact Kennisha C. Tucker at (312) 469–2591 or *Kennisha.Tucker@rrb.gov*. Comments regarding the information collection should be addressed to Brian Foster, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–1275 or emailed to *Brian.Foster@rrb.gov*. Written comments should be received within 60 days of this notice.

Brian D. Foster,

Clearance Officer.

[FR Doc. 2020–03107 Filed 2–14–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88164; File No. SR–CBOE–2020–005]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fees Schedule in Connection With Migration

February 11, 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 January 28, 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 in connection with migration. 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

In 2016, the Exchange's parent company, Cboe Global Markets, Inc. (formerly named CBOE Holdings, Inc.) (''Cboe Global''), which is also the parent company of Cboe C2 Exchange, Inc. (''C2''), acquired Cboe EDGA Exchange, Inc. (''EDGA''), Cboe EDGX Exchange, Inc. (''EDGX'' or ''EDGX Options''), Cboe BZX Exchange, Inc. (''BZX'' or ''BZX Options''), and Cboe BYX Exchange, Inc. (''BYX'' and, together with Cboe Options, C2, EDGX, EDGA, and BZX, the ''Affiliated Exchanges''). The Cboe Affiliated Exchanges recently aligned certain system functionality, including with respect to connectivity, retaining only intended differences between the Affiliated Exchanges, in the context of a technology migration. The Exchange migrated its trading platform to the same system used by the Affiliated Exchanges, which the Exchange completed on October 7, 2019 (the ''migration''). As a result of this migration, the Exchange's pre-migration connectivity architecture was rendered obsolete, and as such, the Exchange now offers new functionality, including new logical connectivity, and therefore proposes to adopt corresponding fees.[3] In determining the proposed fee changes, the Exchange assessed the impact on market participants to ensure that the proposed fees would not create an undue financial burden on any market participants, including smaller market participants. While the Exchange has no way of predicting with certainty the impact of the proposed changes, the Exchange had anticipated its post-migration connectivity revenue[4] to be approximately 1.75% lower than connectivity revenue pre-migration.[5] In addition to providing a consistent technology offering across the Cboe Affiliated Exchanges, the migration also provided market participants a latency equalized infrastructure, improved system performance, and increased sustained order and quote per second capacity, as discussed more fully below. Accordingly, in connection with the migration and in order to more closely align the Exchange's fee structure with that of its Affiliated Exchanges, the Exchange intends to update and simplify its fee structure with respect to access and connectivity and adopt new access and connectivity fees.[6]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] As of October 7, 2019, market participants no longer have the ability to connect to the old Exchange architecture.

[4] Connectivity revenue post-migration includes revenue from physical port fees (other than for disaster recovery), Cboe Data Services Port Fee, logical port fees, Trading Permit Fees, Market-Maker EAP Appointment Unit fees, Tier Appointment Surcharges and Floor Broker Trading Surcharges, less the Floor Broker ADV discounts and discounts on BOE Bulk Ports via the Affiliate Volume Plan and the Market-Maker Access Credit program.

[5] The Exchange does not anticipate realizing the projected revenue reduction prior to February 2020, as the Exchange's legacy physical ports will not be decommissioned until January 31, 2020 and firms may still be in the process of transitioning their connectivity. As such, the Exchange believes any changes in revenue until such time are not reflective of the predicted and modeled impact.

[6] The Exchange initially filed the proposed fee changes on October 1, 2019 (SR–CBOE–2019–077). On business date October 2, 2019, the Exchange withdrew that filing and submitted SR–CBOE–2019–082, *See* Securities Exchange Act Release No. 87304 (October 15, 2019), 84 FR 56240, (October 21, 2019) (''Original Filing''). On business date November 29, 2019, Securities Exchange Act Release No. 87727 (December 12, 2019), 84 FR

Continued

Physical Connectivity

A physical port is utilized by a Trading Permit Holder (''TPH'') or non-TPH to connect to the Exchange at the data centers where the Exchange's servers are located. The Exchange currently assesses fees for Network Access Ports for these physical connections to the Exchange. Specifically, TPHs and non-TPHs can elect to connect to Cboe Options' trading system via either a 1 gigabit per second (''Gb'') Network Access Port or a 10 Gb Network Access Port. Pre-migration the Exchange assessed a monthly fee of $1,500 per port for 1 Gb Network Access Ports and a monthly fee of $5,000 per port for 10 Gb Network Access Ports for access to Cboe Options primary system. Through January 31, 2020, Cboe Options market participants will continue to have the ability to connect to Cboe Options' trading system via the current Network Access Ports. As of October 7, 2019, in connection with the migration, TPHs and non-TPHs may alternatively elect to connect to Cboe Options via new latency equalized Physical Ports.[7] The new Physical Ports similarly allow TPHs and non-TPHs the ability to connect to the Exchange at the data center where the Exchange's servers are located and TPHs and non-TPHs have the option to connect via 1 Gb or 10 Gb Physical Ports. As noted above, both the new 1 Gb and 10 Gb Physical Ports provide latency equalization, meaning that each market participant will be afforded the same latency for 1 Gb or 10 Gb Physical Ports in the primary data center to the Exchange's customer-facing switches regardless of location of the market participant's cage[8] in the primary data center relative to the Exchange's servers. Conversely, the legacy Network Access Ports are not latency equalized, meaning the location of a market participant's cage within the data center may affect latency. For example, in the legacy system, a cage located further from the Exchange's servers may experience higher latency than those located closer to the Exchange's servers.[9] As such, the proposed Physical Ports ensure all market participants connected to the Exchange via the new Physical Ports will receive the same respective latency for each port size and ensure that no market participant has a latency advantage over another market participant within the primary data center.[10] Additionally, the new infrastructure utilizes new and faster switches resulting in lower overall latency.

The Exchange proposes to assess the following fees for any physical port, regardless of whether the TPH or non-TPH connects via the current Network Access Ports or the new Physical Ports. Specifically, the Exchange proposes to continue to assess a monthly fee of $1,500 per port for 1 Gb Network Access Ports and new Physical Ports and increase the monthly fee for 10 Gb Network Access Ports and new Physical Ports to $7,000 per port. Physical port fees will be prorated based on the remaining trading days in the calendar month. The proposed fee for 10 Gb Physical Ports is in line with the amounts assessed by other exchanges for similar connections by its Affiliated Exchanges and other Exchanges that utilize the same connectivity infrastructure.[11]

In addition to the benefits resulting from the new Physical Ports providing latency equalization and new switches (*i.e.,* improved latency), TPHs and non-TPHs may be able to reduce their overall physical connectivity fees. Particularly, Network Access Port fees are assessed for unicast (orders, quotes) and multicast (market data) connectivity separately. More specifically, Network Access Ports may only receive one type of connectivity each (thus requiring a market participant to maintain two ports if that market participant desires both types of connectivity). The new Physical Ports however, allow access to both unicast and multicast connectivity with a single physical connection to the Exchange. Therefore, TPHs and non-TPHs that currently purchase two legacy Network Access Ports for the purpose of receiving each type of connectivity now have the option to purchase only one new Physical Port to accommodate their connectivity needs, which may result in reduced costs for physical connectivity.[12]

Cboe Data Services—Port Fees

The Exchange proposes to amend the ''Port Fee'' under the Cboe Data Services (''CDS'') Fees Schedule. Currently, the Port Fee is payable by any Customer[13] that receives data through two types of sources; a direct connection to CDS (''direct connection'') or through a connection to CDS provided by an extranet service provider (''extranet connection''). The Port Fee applies to receipt of any Cboe Options data feed but is only assessed once per data port. The Exchange proposes to amend the monthly CDS Port Fee to provide that it is payable ''per source'' used to receive data, instead of ''per data port''. The Exchange also proposes to increase the fee from $500 per data port/month to $1,000 per data source/month.[14] The

69428, (December 18, 2019) (''Second Proposed Rule Change''). On January 28, 2020 the Exchange withdrew that filing and submitted this filing (''Third Proposed Rule Change'').

[7] As previously noted, market participants will continue to have the option of connecting to Cboe Options via a 1 Gbps or 10 Gbps Network Access Port at the same rates as proposed, respectively.

[8] A market participant's ''cage'' is the cage within the data center that contains a market participant's servers, switches and cabling.

[9] The Exchange equalizes physical connectivity in the data center for its primary system by taking the farthest possible distance that a Cboe market participant cage may exist from the Exchange's customer-facing switches and using that distance as the cable length for any cross-connect.

[10] The Exchange notes that 10 Gb Physical Ports have an 11 microsecond latency advantage over 1 Gb Physical Ports. Other than this difference, there are no other means to receive a latency advantage as compared to another market participant in the new connectivity structure.

[11] *See* Cboe EDGA U.S. Equities Exchange Fee Schedule, Physical Connectivity Fees; Cboe EDGX U.S. Equities Exchange Fee Schedule, Physical Connectivity Fees; Cboe BZX U.S. Equities Exchange Fee Schedule, Physical Connectivity Fees; Cboe BYX U.S. Equities Exchange Fee Schedule, Physical Connectivity Fees; Cboe EDGX Options Exchange Fee Schedule, Physical Connectivity Fees; and Cboe BZX Options Exchange Fee Schedule, Physical Connectivity Fees (collectively, ''Affiliated Exchange Fee Schedules''). *See e.g.,* Nasdaq PHLX and ISE Rules, General Equity and Options Rules, General 8. Phlx and ISE each charge a monthly fee of $2,500 for each 1Gb connection, $10,000 for each 10Gb connection and $15,000 for each 10Gb Ultra connection. *See also* Nasdaq Price List—Trading Connectivity. Nasdaq charges a monthly fee of $7,500 for each 10Gb direct connection to Nasdaq and $2,500 for each direct connection that supports up to 1Gb. *See also* NYSE American Fee Schedule, Section V.B, and Arca Fees and Charges, Co-Location Fees. NYSE American and Arca each charge a monthly fee of $5,000 for each 1Gb circuit, $14,000 for each 10Gb circuit and $22,000 for each 10Gb LX circuit.

[12] The Exchange proposes to eliminate the current Cboe Command Connectivity Charges table in its entirety and create and relocate such fees in a new table in the Fees Schedule that addresses fees for physical connectivity, including fees for the current Network Access Ports, the new Physical Ports and Disaster Recovery (''DR'') Ports. The Exchange notes that it is not proposing any changes with respect to DR Ports other than renaming the DR ports from ''Network Access Ports'' to ''Physical Ports'' to conform to the new Physical Port terminology. The Exchange also notes that subsequent to the initial filings that proposed these fee changes on October 1 and 2, 2019 (SR–CBOE–2019–077 and SR–CBOE–2019–082), the Exchange amended the proposed port fees to waive fees for ports used for PULSe in filing No. SR–CBOE–2019–105. The additions proposed by filing SR–CBOE–2019–105 are double underlined in Exhibit 5A and the deletions are doubled bracketed in Exhibit 5A.

[13] A Customer is any person, company or other entity that, pursuant to a market data agreement with CDS, is entitled to receive data, either directly from CDS or through an authorized redistributor (*i.e.,* a Customer or extranet service provider), whether that data is distributed externally or used internally.

[14] For example, under the pre-migration ''per port'' methodology, if a TPH maintained 4 ports that receive market data, that TPH would be assessed $2,000 per month (*i.e.,* $500 × 4 ports), regardless of how many sources it used to receive data. Under the proposed ''per source'' methodology, if a TPH maintains 4 ports that

Exchange notes the proposed change in assessing the fee (*i.e.,* per source vs per port) and the proposed fee amount are the same as the corresponding fee on its affiliate C2.[15]

In connection with the proposed change, the Exchange also proposes to rename the ''Port Fee'' to ''Direct Data Access Fee''. As the fee will be payable ''per data source'' used to receive data, instead of ''per data port'', the Exchange believes the proposed name is more appropriate and that eliminating the term ''port'' from the fee will eliminate confusion as to how the fee is assessed.

Logical Connectivity

Next, the Exchange proposes to amend its login fees. By way of background, Cboe Options market participants were able to access Cboe Command via either a CMI or a FIX Port, depending on how their systems are configured. Effective October 7, 2019, market participants are no longer able to use CMI and FIX Login IDs. Rather, the Exchange utilizes a variety of logical connectivity ports as further described below. Both a legacy CMI/FIX Login ID and logical port represent a technical port established by the Exchange within the Exchange's trading system for the delivery and/or receipt of trading messages—*i.e.,* orders, accepts, cancels, transactions, etc. Market participants that wish to connect directly to the Exchange can request a number of different types of ports, including ports that support order entry, customizable purge functionality, or the receipt of market data. Market participants can also choose to connect indirectly through a number of different third-party providers, such as another broker-dealer or service bureau that the Exchange permits through specialized access to the Exchange's trading system and that may provide additional services or operate at a lower mutualized cost by providing access to multiple members. In light of the discontinuation of CMI and FIX Login IDs, the Exchange proposes to eliminate the fees associated with the CMI and FIX login IDs and adopt the below pricing for logical connectivity in its place.

Service	Cost per month
Logical Ports (BOE, FIX) 1 to 5.	$750 per port.
Logical Ports (BOE, FIX) >5.	$800 per port.
Logical Ports (Drop)	$750 per port.
BOE Bulk Ports 1 to 5	$1,500 per port.
BOE Bulk Ports 6 to 30	$2,500 per port.
BOE Bulk Ports >30	$3,000 per port.
Purge ports	$850 per port.
GRP Ports	$750/primary (A or C Feed).
Multicast PITCH/Top Spin Server Ports.	$750/set of primary (A or C feed).

The Exchange proposes to provide for each of the logical connectivity fees that new requests will be prorated for the first month of service. Cancellation requests are billed in full month increments as firms are required to pay for the service for the remainder of the month, unless the session is terminated within the first month of service. The Exchange notes that the proration policy is the same on its Affiliated Exchanges.[16]

Logical Ports (BOE, FIX, Drop): The new Logical Ports represent ports established by the Exchange within the Exchange's system for trading purposes. Each Logical Port established is specific to a TPH or non-TPH and grants that TPH or non-TPH the ability to operate a specific application, such as order/quote[17] entry (FIX and BOE Logical Ports) or drop copies (Drop Logical Ports). Similar to CMI and FIX Login IDs, each Logical Port will entitle a firm to submit message traffic of up to specified number of orders per second.[18] The Exchange proposes to assess $750 per port per month for all Drop Logical Ports and also assess $750 per port per month (which is the same amount currently assessed per CMI/FIX Login ID per month), for the first 5 FIX/BOE Logical Ports and thereafter assess $800 per port, per month for each additional FIX/BOE Logical Port. While the proposed ports will be assessed the same monthly fees as current CMI/FIX Login IDs (for the first five logical ports), the proposed logical ports provide for significantly more message traffic as shown below:

	CMI/FIX login Ids		BOE/FIX logical ports
	Quotes	Orders	Quotes/orders
Bandwidth Limit per login	5,000 quotes/3 sec[19]	30 orders/sec	15,000 quotes/orders/3 sec.
Cost	$750 each	$750 each	$750/$800 each.
Cost per Quote/Order Sent @Limit	$0.15 per quote/3 sec	$25.00 per order/sec	$0.05/$0.053 per quote/order/3 sec.

Logical Port fees will be limited to Logical Ports in the Exchange's primary data center and no Logical Port fees will be assessed for redundant secondary data center ports. Each BOE or FIX Logical Port will incur the logical port fee indicated in the table above when used to enter up to 70,000 orders per trading day per logical port as measured on average in a single month. Each incremental usage of up to 70,000 per day per logical port will incur an additional logical port fee of $800 per month. Incremental usage will be determined on a monthly basis based on the average orders per day entered in a single month across all of a market participant's subscribed BOE and FIX Logical Ports. The Exchange believes that the pricing implications of going beyond 70,000 orders per trading day per Logical Port encourage users to mitigate message traffic as necessary. The Exchange notes that the proposed fee of $750 per port is the same amount assessed not only for current CMI and

receive market data, but receives data through only one source (*e.g.,* a direct connection) that TPH would be assessed $1,000 per month (*i.e.,* $1000 x 1 source). If that TPH maintains 4 ports but receives data from both a direct connection and an extranet connection, that TPH would be assessed $2,000 per month (*i.e.,* $1,000 × 2 sources). Similarly, if that TPH maintains 4 ports and receives data from two separate extranet providers, that TPH would be assessed $2,000 per month (*i.e.,* $1,000 × 2).

[15] *See* Cboe C2 Options Exchange Fee Schedule, Cboe Data Services, LLC Fees, Section IV, Systems Fees.

[16] *See* Affiliated Exchange Fee Schedules, Logical Port Fees.

[17] As of October 7, 2019, the definition of quote in Cboe Options Rule 1.1 means a firm bid or offer a Market-Maker (a) submits electronically as an order or bulk message (including to update any bid or offer submitted in a previous order or bulk message) or (b) represents in open outcry on the trading floor.

[18] Login Ids restrict the maximum number of orders and quotes per second in the same way logical ports do, and Users may similarly have multiple logical ports as they may have Trading Permits and/or bandwidth packets to accommodate their order and quote entry needs.

[19] Each Login ID has a bandwidth limit of 80,000 quotes per 3 seconds. However, in order to place such bandwidth onto a single Login ID, a TPH or non-TPH would need to purchase a minimum of 15 Market-Maker Permits or Bandwidth Packets (each Market-Maker Permit and Bandwidth Packet provides 5,000 quotes/3 sec). For purposes of comparing ''quote'' bandwidth, the provided example assumes only 1 Market-Maker Permit or Bandwidth Packet has been purchased.

[20] *See* Cboe BZX Options Exchange Fee Schedule, Options Logical Port Fees.

FIX Login Ids, but also similar ports available on an affiliate exchange.[20]

The Exchange also proposes to provide that the fee for one FIX Logical Port connection to PULSe and one FIX Logical Port connection to Cboe Silexx (for FLEX trading purposes) will be waived per TPH. The Exchange notes that only one FIX Logical Port connection is required to support a firm's access through each of PULSe and Cboe Silexx FLEX.

BOE Bulk Logical Ports: The Exchange also offers BOE Bulk Logical Ports, which provide users with the ability to submit single and bulk order messages to enter, modify, or cancel orders designated as Post Only Orders with a Time-in-Force of Day or GTD with an expiration time on that trading day. While BOE Bulk Ports will be available to all market participants, the Exchange anticipates they will be used primarily by Market-Makers or firms that conduct similar business activity, as the primary purpose of the proposed bulk message functionality is to encourage market-maker quoting on exchanges. As indicated above, BOE Bulk Logical Ports are assessed $1,500 per port, per month for the first 5 BOE Bulk Logical Ports, assessed $2,500 per port, per month thereafter up to 30 ports and thereafter assessed $3,000 per port, per month for each additional BOE Bulk Logical Port. Like CMI and FIX Login IDs, and FIX/BOX Logical Ports, BOE Bulk Ports will also entitle a firm to submit message traffic of up to specified number of quotes/orders per second.[21] The proposed BOE Bulk ports also provide for significantly more message traffic as compared to current CMI/FIX Login IDs, as shown below:

	CMI/FIX login Ids	BOE bulk ports
	Quotes	Quotes[22]
Bandwidth Limit	5,000 quotes/3 sec[23]	225,000 quotes 3 sec.
Cost	$750 each	$1,500/$2,500/$3,000 each.
Cost per Quote/Order Sent @Limit	$0.15 per quote/3 sec	$0.006/$0.011/$0.013 per quote/3 sec.

Each BOE Bulk Logical Port will incur the logical port fee indicated in the table above when used to enter up to 30,000,000 orders per trading day per logical port as measured on average in a single month. Each incremental usage of up to 30,000,000 orders per day per BOE Bulk Logical Port will incur an additional logical port fee of $3,000 per month. Incremental usage will be determined on a monthly basis based on the average orders per day entered in a single month across all of a market participant's subscribed BOE Bulk Logical Ports. The Exchange believes that the pricing implications of going beyond 30,000,000 orders per trading day per BOE Bulk Logical Port encourage users to mitigate message traffic as necessary. The Exchange notes that the proposed BOE Bulk Logical Port fees are similar to the fees assessed for these ports by BZX Options.[24]

Purge Ports: As part of the migration, the Exchange introduced Purge Ports to provide TPHs additional risk management and open order control functionality. Purge ports were designed to assist TPHs, in the management of, and risk control over, their quotes, particularly if the TPH is dealing with a large number of options. Particularly, Purge Ports allow TPHs to submit a cancelation for all open orders, or a subset thereof, across multiple sessions under the same Executing Firm ID (''EFID''). This would allow TPHs to seamlessly avoid unintended executions, while continuing to evaluate the direction of the market. While Purge Ports are available to all market participants, the Exchange anticipates they will be used primarily by Market-Makers or firms that conduct similar business activity and are therefore exposed to a large amount of risk across a number securities. The Exchange notes that market participants are also able to cancel orders through FIX/BOE Logical Ports and as such a dedicated Purge Port is not required nor necessary. Rather, Purge Ports were specially developed as an optional service to further assist firms in effectively managing risk. As indicated in the table above, the Exchange proposes to assess a monthly charge of $850 per Purge Port. The Exchange notes that the proposed fee is in line with the fee assessed by other exchanges, including its Affiliated Exchanges, for Purge Ports.[25]

Multicast PITCH/Top Spin Server and GRP Ports: In connection with the migration, the Exchange also offers optional Multicast PITCH/Top Spin Server (''Spin'') and GRP ports and proposes to assess $750 per month, per port. Spin Ports and GRP Ports are used to request and receive a retransmission of data from the Exchange's Multicast PITCH/Top data feeds. The Exchange's Multicast PITCH/Top data feeds are available from two primary feeds, identified as the ''A feed'' and the ''C feed'', which contain the same information but differ only in the way such feeds are received. The Exchange also offers two redundant feeds, identified as the ''B feed'' and the ''D feed.'' All secondary feed Spin and GRP Ports will be provided for redundancy at no additional cost. The Exchange notes a dedicated Spin and GRP Port is not required nor necessary. Rather, Spin ports enable a market participant to receive a snapshot of the current book quickly in the middle of the trading session without worry of gap request limits and GRP Ports were specially developed to request and receive retransmission of data in the event of missed or dropped message. The Exchange notes that the proposed fee is in line with the fee assessed for the same ports on BZX Options.[26]

Access Credits

The Exchange next proposes to amend its Affiliate Volume Plan (''AVP'') to provide Market-Makers an opportunity to obtain credits on their monthly BOE

[21] The Exchange notes that while technically there is no bandwidth limit per BOE Bulk Port, there may be possible performance degradation at 15,000 messages per second (which is the equivalent of 225,000 quotes/orders per 3 seconds). As such, the Exchange uses the number at which performance may be degraded for purposes of comparison.

[22] *See* Cboe Options Rule 1.1.

[23] Each Login ID has a bandwidth limit of 80,000 quotes per 3 seconds. However, in order to place such bandwidth onto a single Login ID, a TPH or non-TPH would need to purchase a minimum of 15 Market-Maker Permits or Bandwidth Packets (each Market-Maker Permit and Bandwidth Packet provides 5,000 quotes/3 sec). For purposes of comparing ''quote'' bandwidth, the provided example assumes only 1 Market-Maker Permit or Bandwidth Packet has been purchased.

[24] *See* Cboe BZX Options Exchange Fee Schedule, Options Logical Port Fees.

[25] *See e.g.,* Nasdaq ISE Options Pricing Schedule, Section 7(C), Ports and Other Services. *See also* Cboe EDGX Options Exchange Fee Schedule, Options Logical Port Fees; Cboe C2 Options Exchange Fee Schedule, Options Logical Port Fees and Cboe BZX Options Exchange Fee Schedule, Options Logical Port Fees.

[26] *See* Cboe BZX Options Exchange Fee Schedule, Options Logical Port Fees.

Bulk Port Fees.[27] By way of background, under AVP, if a TPH Affiliate [28] or Appointed OFP [29] (collectively, an ''affiliate'') of a Market-Maker qualifies under the Volume Incentive Program (''VIP'') (*i.e.,* achieves VIP Tiers 2–5), that Market-Maker will also qualify for a discount on that Market-Maker's Liquidity Provider (''LP'') Sliding Scale transaction fees and Trading Permit fees. The Exchange proposes to amend AVP to provide that qualifying Market-Makers will receive a discount on Bulk Port fees (instead of Trading Permits) where an affiliate achieves VIP Tiers 4 or 5. As discussed more fully below, the Exchange is amending its Trading Permit structure, such that off-floor Market-Makers no longer need to hold more than one Market-Maker Trading Permit. As such, in place of credits for Trading Permits, the Exchange will provide credits for BOE Bulk Ports.[30] The proposed credits are as follows:

Market Maker affiliate access credit	VIP tier	Percent credit on monthly BOE bulk port fees
Credit Tier	1	0
	2	0
	3	0
	4	15
	5	25

The Exchange believes the proposed change to AVP continues to allow the Exchange to provide TPHs that have both Market-Maker and agency operations reduced Market-Maker costs via the credits, albeit credits on BOE Bulk Port fees instead of Trading Permit fees. AVP also continues to provide incremental incentives for TPHs to strive for the higher tier levels, which provide increasingly higher benefits for satisfying increasingly more stringent criteria.

In addition to the opportunity to receive credits via AVP, the Exchange proposes to provide an additional opportunity for Market-Makers to obtain credits on their monthly BOE Bulk Port fees based on the previous month's make rate percentage. By way of background, the Liquidity Provider Sliding Scale Adjustment Table provides that Taker fees be applied to electronic ''Taker'' volume and a Maker rebate be applied to electronic ''Maker'' volume, in addition to the transaction fees assessed under the Liquidity Provider Sliding Scale.[31] The amount of the Taker fee (or Maker rebate) is determined by the Liquidity Provider's percentage of volume from the previous month that was Maker (''Make Rate'').[32] Market-Makers are given a Performance Tier based on their Make Rate percentage which currently provides adjustments to transaction fees. Thus, the program is designed to attract liquidity from traditional Market-Makers. The Exchange proposes to now also provide BOE Bulk Port fee credits if Market-Makers satisfy the thresholds of certain Performance Tiers. Particularly, the Performance Tier earned will also determine the percentage credit applied to a Market-Maker's monthly BOE Bulk Port fees, as shown below:

Market Maker access credit	Liquidity provider sliding scale adjustment performance tier	Make rate (percent based on prior month)	Percent credit on monthly BOE bulk port fees
Credit Tier	1	0–50	0
	2	Above 50–60	0
	3	Above 60–75	0
	4	Above 75–90	40
	5	Above 90	40

The Exchange believes the proposal mitigates costs incurred by traditional Market-Makers that focus on adding liquidity to the Exchange (as opposed to those that provide and take, or just take). The Exchange lastly notes that both the Market-Maker Affiliate Access Credit under AVP and the Market-Maker Access Credit tied to Performance Tiers can both be earned by a TPH, and these credits will each apply to the total monthly BOE Bulk Port Fees including any incremental BOE Bulk Port fees incurred, before any credits/adjustments have been applied (*i.e.,* an electronic MM can earn a credit from 15% to 65%).

Bandwidth Packets

As described above, post-migration, the Exchange utilizes a variety of logical ports. Part of this functionality is similar to bandwidth packets that were previously available on the Exchange. Bandwidth packets restricted the maximum number of orders and quotes per second. Post-migration, market participants may similarly have multiple Logical Ports and/or BOE Bulk Ports as they may have had bandwidth packets to accommodate their order and quote entry needs. As such, the Exchange proposes to eliminate all of

[27] As noted above, while BOE Bulk Ports will be available to all market participants, the Exchange anticipates they will be used primarily by Market Makers or firms that conduct similar business activity.

[28] For purposes of AVP, ''Affiliate'' is defined as having at least 75% common ownership between the two entities as reflected on each entity's Form BD, Schedule A.

[29] *See* Cboe Options Fees Schedule Footnote 23. Particularly, a Market-Maker may designate an Order Flow Provider (''OFP'') as its ''Appointed OFP'' and an OFP may designate a Market-Maker to be its ''Appointed Market-Maker'' for purposes of qualifying for credits under AVP.

[30] The Exchange notes that Trading Permits currently each include a set bandwidth allowance and 3 logins. Current logins and bandwidth are akin to the proposed logical ports, including BOE Bulk Ports which will primarily be used by Market-Makers.

[31] *See* Cboe Options Exchange Fees Schedule, Liquidity Provider Sliding Scale Adjustment Table.

[32] More specifically, the Make Rate is derived from a Liquidity Provider's electronic volume the previous month in all symbols excluding Underlying Symbol List A using the following formula: (i) The Liquidity Provider's total electronic automatic execution (''auto-ex'') volume (*i.e.,* volume resulting from that Liquidity Provider's resting quotes or single sided quotes/orders that were executed by an incoming order or quote), divided by (ii) the Liquidity Provider's total auto-ex volume (*i.e.,* volume that resulted from the Liquidity Provider's resting quotes/orders and volume that resulted from that LP's quotes/orders that removed liquidity). For example, a TPH's electronic Make volume in September 2019 is 2,500,000 contracts and its total electronic auto-ex volume is 3,000,000 contracts, resulting in a Make Rate of 83% (Performance Tier 4). As such, the TPH would receive a 40% credit on its monthly Bulk Port fees for the month of October 2019. For the month of October 2019, the Exchange will be billing certain incentive programs separately, including the Liquidity Provider Sliding Scale Adjustment Table, for the periods of October 1–October 4 and October 7–October 31 in light of the migration of its billing system. As such, a Market-Maker's Performance Tier for November 2019 will be determined by the Market-Maker's percentage of volume that was Maker from the period of October 7–October 31, 2019.

the current Bandwidth Packet fees.[33] The Exchange believes that the proposed pricing implications of going beyond specified bandwidth described above in the logical connectivity fees section will be able to otherwise mitigate message traffic as necessary.

CAS Servers

By way of background, in order to connect to the legacy Cboe Command, which allowed a TPH to trade on the Cboe Options System, a TPH had to connect via either a CMI or FIX interface (depending on the configuration of the TPH's own systems). For TPHs that connected via a CMI interface, they had to use CMI CAS Servers. In order to ensure that a CAS Server was not overburdened by quoting activity for Market-Makers, the Exchange allotted each Market-Maker a certain number of CASs (in addition to the shared backups) based on the amount of quoting bandwidth that they had. The Exchange no longer uses CAS Servers, post-migration. In light of the elimination of CAS Servers, the Exchange proposes to eliminate the CAS Server allotment table and extra CAS Server fee.

Trading Permit Fees

By way of background, the Exchange may issue different types of Trading Permits and determine the fees for those Trading Permits.[34] Pre-migration, the Exchange issued the following three types of Trading Permits: (1) Market-Maker Trading Permits, which were assessed a monthly fee of $5,000 per permit; (2) Floor Broker Trading Permits, which were assessed a monthly fee of $9,000 per permit; and (3) Electronic Access Permits (''EAPs''), which were assessed a monthly fee of $1,600 per. The Exchange also offered separate Market-Maker and Electronic Access Permits for the Global Trading Hours (''GTH'') session, which were assessed a monthly fee of $1,000 per permit and $500 per permit respectively.[35] For further color, a Market-Maker Trading Permit entitled the holder to act as a Market-Maker, including a Market-Maker trading remotely, DPM, eDPM, or LMM, and also provided an appointment credit of 1.0, a quoting and order entry bandwidth allowance, up to three logins, trading floor access and TPH status.[36] A Floor Broker Trading Permit entitled the holder to act as a Floor Broker, provided an order entry bandwidth allowance, up to 3 logins, trading floor access and TPH status.[37] Lastly, an EAP entitled the holder to electronic access to the Exchange. Holders of EAPs must have been broker-dealers registered with the Exchange in one or more of the following capacities: (a) Clearing TPH, (b) TPH organization approved to transact business with the public, (c) Proprietary TPHs and (d) order service firms. The permit did not provide access to the trading floor. An EAP also provided an order entry bandwidth allowance, up to 3 logins and TPH status.[38] The Exchange also provided an opportunity for TPHs to pay reduced rates for Trading Permits via the Market Maker and Floor Broker Trading Permit Sliding Scale Programs (''TP Sliding Scales''). Particularly, the TP Sliding Scales allowed Market-Makers and Floor Brokers to pay reduced rates for their Trading Permits if they committed in advance to a specific tier that includes a minimum number of eligible Market-Maker and Floor Broker Trading Permits, respectively, for each calendar year.[39]

As noted above, Trading Permits were tied to bandwidth allocation, logins and appointment costs, and as such, TPH organizations may hold multiple Trading Permits of the same type in order to meet their connectivity and appointment cost needs. Post-Migration, bandwidth allocation, logins and appointment costs are no longer tied to a Trading Permit, and as such, the Exchange proposes to modify its Trading Permit structure. Particularly, in connection with the migration, the Exchange adopted separate on-floor and off-floor Trading Permits for Market-Makers and Floor Brokers, adopted a new Clearing TPH Permit, and proposes to modify the corresponding fees and discounts. As was the case pre-migration, the proposed access fees discussed below will continue to be non-refundable and will be assessed through the integrated billing system during the first week of the following month. If a Trading Permit is issued during a calendar month after the first trading day of the month, the access fee for the Trading Permit for that calendar month is prorated based on the remaining trading days in the calendar month. Trading Permits will be renewed automatically for the next month unless the Trading Permit Holder submits written notification to the Membership Services Department by 4 p.m. CT on the second-to-last business day of the prior month to cancel the Trading Permit effective at or prior to the end of the applicable month. Trading Permit Holders will only be assessed a single monthly fee for each type of electronic Trading Permit it holds.

First, TPHs no longer need to hold multiple permits for each type of electronic Trading Permit (*i.e.,* electronic Market-Maker Trading Permits and/or and Electronic Access Permits). Rather, for electronic access to the Exchange, a TPH need only purchase one of the following permit types for each trading function the TPH intends to perform: Market-Maker Electronic Access Permit (''MM EAP'') in order to act as an off-floor Market-Maker and which will continue to be assessed a monthly fee of $5,000, Electronic Access Permit (''EAP'') in order to submit orders electronically to the Exchange[40] and which will be assessed a monthly fee of $3,000, and a Clearing TPH Permit, for TPHs acting solely as a Clearing TPH, which will be assessed a monthly fee of $2,000 (and is more fully described below). For example, a TPH organization that wishes to act as a Market-Maker and also submit orders electronically in a non-Market Maker capacity would have to purchase one MM EAP and one EAP. TPHs will be assessed the monthly fee for each type of Permit once per electronic access capacity.

Next, the Exchange proposes to adopt a new Trading Permit, exclusively for Clearing TPHs that are approved to act solely as a Clearing TPH (as opposed to those that are also approved in a capacity that allows them to submit orders electronically). Currently any TPH that is registered to act as a Clearing TPH must purchase an EAP, whether or not that Clearing TPH acts solely as a Clearing TPH or acts as a Clearing TPH and submits orders electronically. The Exchange proposes to adopt a new Trading Permit, for any TPH that is registered to act solely as Clearing TPH at a discounted rate of $2,000 per month.[41]

[33] *See* Cboe Options Fees Schedule, Bandwidth Packet Fees.

[34] *See* Cboe Options Rules 3.1(a)(iv)–(v).

[35] The fees were waived through September 2019 for the first Market-Maker and Electronic Access GTH Trading Permits.

[36] *See* Cboe Options Fees Schedule.

[37] Id.

[38] Id.

[39] Due to the October 7 migration, the Exchange had amended the TP Sliding Scale Programs to provide that any commitment to Trading Permits under the TP Sliding Scales shall be in place through September 2019, instead of the calendar year. *See* Cboe Options Fees Schedule, Footnotes 24 and 25.

[40] EAPs may be purchased by TPHs that both clear transactions for other TPHs (*i.e.,* a ''Clearing TPH'') and submit orders electronically.

[41] Cboe Option Rules provides the Exchange authority to issue different types of Trading Permits which allows holders, among other things, to act in one or more trading functions authorized by the Rules. *See* Cboe Options Rule 3.1(a)(iv). The Exchange notes that currently 17 out of 38 Clearing TPHs are acting solely as a Clearing TPH on the Exchange.

Additionally, the Exchange proposes to eliminate its fees for Global Trading Hours Trading Permits. Particularly, the Exchange proposes to provide that any Market-Maker EAP, EAP and Clearing TPH Permit provides access (at no additional cost) to the GTH session.[42] Additionally, the Exchange proposes to amend Footnote 37 of the Fees Schedule regarding GTH in connection with the migration. Currently Footnote 37 provides that separate access permits and connectivity is needed for the GTH session. The Exchange proposes to eliminate this language as that is no longer the case post-migration (*i.e.,* an electronic Trading Permits will grant access to both sessions and physical and logical ports may be used in both sessions, eliminating the need to purchase separate connectivity). The Exchange also notes that in connection with migration, the Book used during Regular Trading Hours (''RTH'') will be the same Book used during GTH (as compared to pre-migration where the Exchange maintained separate Books for each session). The Exchange therefore also proposes to eliminate language in Footnote 37 stating that GTH is a segregated trading session and that there is no market interaction between the two sessions.

The Exchange next proposes to adopt MM EAP Appointment fees. By way of background, a registered Market-Maker may currently create a Virtual Trading Crowd (''VTC'') Appointment, which confers the right to quote electronically in an appropriate number of classes selected from ''tiers'' that have been structured according to trading volume statistics, except for the AA tier.[43] Each Trading Permit historically held by a Market-Maker had an appointment credit of 1.0. A Market-Maker could select for each Trading Permit the Market-Maker held any combination of classes whose aggregate appointment cost did not exceed 1.0. A Market-Maker could not hold a combination of appointments whose aggregate appointment cost was greater than the number of Trading Permits that Market-Maker held.[44]

As discussed, post-migration, bandwidth allocation, logins and appointment costs are no longer tied to a single Trading Permit and therefore TPHs no longer need to have multiple permits for each type of electronic Trading Permit. Market-Makers must still select class appointments in the classes they seek to make markets electronically.[45] Particularly, a Market-Maker firm will only be required to have one permit and will thereafter be charged for one or more ''Appointment Units'' (which will scale from 1 ''unit'' to more than 5 ''units''), depending on which classes they elect appointments in. Appointment Units will replace the standard 1.0 appointment cost, but function in the same manner. Appointment weights (formerly known as ''appointment costs'') for each appointed class will be set forth in Cboe Options Rule 5.50(g) and will be summed for each Market-Maker in order to determine the total appointment units, to which fees will be assessed. This was the manner in which the tier costs per class appointment were summed to meet the 1.0 appointment cost, the only difference being that if a Market-Maker exceeds this ''unit'', then their fees will be assessed under the ''unit'' that corresponds to the total of their appointment weights, as opposed to holding another Trading Permit because it exceeded the 1.0 ''unit''. Particularly, the Exchange proposes to adopt a new MM EAP Appointment Sliding Scale. Appointment Units for each assigned class will be aggregated for each Market-Maker and Market-Maker affiliate. If the sum of appointments is a fractional amount, the total will be rounded up to the next highest whole Appointment Unit. The following lists the progressive monthly fees for Appointment Units:[46]

Market-maker EAP appointments	Quantity	Monthly fees (per unit)
Appointment Units.	1	$0
	2	6,000
	3 to 5	4,000
	>5	3,100

As noted above, upon migration the Exchange required separate Trading Permits for on-floor and off-floor activity. As such, the Exchange proposes to maintain a Floor Broker Trading Permit and adopt a new Market-Maker Floor Permit for on-floor Market-Makers. In addition, RUT, SPX, and VIX Tier Appointment fees will be charged separately for Permit, as discussed more fully below.

As briefly described above, the Exchange currently maintains TP Sliding Scales, which allow Market-Makers and Floor Brokers to pay reduced rates for their Trading Permits if they commit in advance to a specific tier that includes a minimum number of eligible Market-Maker and Floor Broker Trading Permits, respectively, for each calendar year. The Exchange proposes to eliminate the current TP Sliding Scales, including the requirement to commit to a specific tier, and replace it with new TP Sliding Scales as follows:[47]

Floor TPH permits	Current permit qty	Current monthly fee (per permit)	Proposed permit qty	Proposed monthly fee (per permit)
Market-Maker Floor Permit	1–10	$5,000	1	$6,000
	11–20	3,700	2 to 5	4,500
	21 or more	1,800	6 to 10	3,500
			>10	2,000
Floor Broker Permit	1	9,000	1	7,500
	2–5	5,000	2 to 3	5,700
	6 or more	3,000	4 to 5	4,500
			>5	3,200

[42] The Exchange notes that Clearing TPHs must be properly authorized by the Options Clearing Corporation (''OCC'') to operate during the Global Trading Hours session and all TPHs must have a Letter of Guarantee to participate in the GTH session (as is the case today).

[43] *See* Cboe Options Rule 5.50 (Appointment of Market-Makers).

[44] For example, if a Market-Maker selected a combination of appointments that has an aggregate appointment cost of 2.5, that Market-Maker must hold at least 3 Market-Maker Trading Permits.

[45] *See* Cboe Options Rule 5.50(a).

[46] For example, if a Market-Maker's total appointment costs amount to 3.5 unites, the Market-Maker will be assessed a total monthly fee of $14,000 (1 appointment unit at $0, 1 appointment unit at $6,000 and 2 appointment units at $4,000) as and for appointment fees and $5,000 for a Market-Maker Trading Permit, for a total monthly sum of $19,000, where a Market-Maker currently (*i.e.,* prior to migration) with a total appointment cost of 3.5 would need to hold 4 Trading Permits and would therefore be assessed a monthly fee of $20,000.

[47] In light of the proposed change to eliminate the TP Sliding Scale, the Exchange proposes to eliminate Footnote 24 in its entirety.

Floor Broker ADV Discount

Footnote 25, which governs rebates on Floor Broker Trading Permits, currently provides that any Floor Broker that executes a certain average of customer or professional customer/voluntary customer (collectively ''customer'') open-outcry contracts per day over the course of a calendar month in all underlying symbols excluding Underlying Symbol List A (except RLG, RLV, RUI, and UKXM), DJX, XSP, and subcabinet trades (''Qualifying Symbols''), will receive a rebate on that TPH's Floor Broker Trading Permit Fees. Specifically, any Floor Broker Trading Permit Holder that executes an average of 15,000 customer (''C'' origin code) and/or professional customer and voluntary customer (''W'' origin code) open-outcry contracts per day over the course of a calendar month in Qualifying Symbols will receive a rebate of $9,000 on that TPH's Floor Broker Trading Permit fees. Additionally, any Floor Broker that executes an average of 25,000 customer open-outcry contracts per day over the course of a calendar month in Qualifying Symbols will receive a rebate of $14,000 on that TPH's Floor Broker Trading Permit fees. The Exchange proposes to maintain, but modify, its discount for Floor Broker Trading Permit fees. First, the measurement criteria to qualify for a rebate will be modified to only include customer (''C'' origin code) open-outcry contracts executed per day over the course of a calendar month in all underlying symbols, while the rebate amount will be modified to be a percentage of the TPH's Floor Broker Permit total costs, instead of a straight rebate.[48] The criteria and corresponding percentage rebates are noted below.[49]

Floor broker ADV discount tier	ADV	Floor broker permit rebate
1	0 to 99,999	0
2	100,000 to 174,999	15
3	>174,999	25

Next, the Exchange proposes to modify its SPX, VIX and RUT Tier Appointment Fees. Currently, these fees are assessed to any Market-Maker TPH that either (i) has the respective SPX, VIX or RUT appointment at any time during a calendar month and trades a specified number of contracts or (ii) trades a specified number of contracts in open outcry during a calendar month. More specifically, the Fees Schedule provides that the $3,000 per month SPX Tier Appointment is assessed to any Market-Maker Trading Permit Holder that either (i) has an SPX Tier Appointment at any time during a calendar month and trades at least 100 SPX contracts while that appointment is active or (ii) conducts any open outcry transaction in SPX or SPX Weeklys at any time during the month. The $2,000 per month VIX Tier Appointment is assessed to any Market-Maker Trading Permit Holder that either (i) has an SPX Tier Appointment at any time during a calendar month and trades at least 100 VIX contracts while that appointment is active or (ii) conducts at least 1000 open outcry transaction in VIX at any time during the month. Lastly, the $1,000 RUT Tier Appointment is assessed to any Market-Maker Trading Permit Holder that either (i) has an RUT Tier Appointment at any time during a calendar month and trades at least 100 RUT contracts while that appointment is active or (ii) conducts at least 1000 open outcry transaction in RUT at any time during the month.

Because the Exchange is separating Market-Maker Trading Permits for electronic and open-outcry market-making, the Exchange will be assessing separate Tier Appointment Fees for each type of Market-Maker Trading Permit. The Exchange proposes that a MM EAP will be assessed the Tier Appointment Fee whenever the Market-Maker executes the corresponding specified number of contracts, if any. The Exchange also proposes to modify the threshold number of contracts a Market-Maker must execute in a month to trigger the fee for SPX, VIX and RUT. Particularly, for SPX, the Exchange proposes to eliminate the 100 contract threshold for electronic SPX executions.[50] The Exchange notes that historically, all TPHs that trade SPX electronically executed more than 100 contracts electronically each month (*i.e.,* no TPH electronically traded between 1 and 100 contracts of SPX). As no TPH would currently be negatively impacted by this change, the Exchange proposes to eliminate the threshold for SPX and align the electronic SPX Tier Appointment Fee with that of the floor SPX Tier Appointment Fee, which is not subject to any executed volume threshold. For the VIX and RUT Tier appointments, the Exchange proposes to increase the threshold from 100 contracts a month to 1,000 contracts a month. The Exchange notes the Tier Appointment Fee amounts are not changing.[51] In connection with the proposed changes, the Exchange proposes to relocate the Tier Appointment Fees to a new table and eliminate the language in the current respective notes sections of each Tier Appointment Fee as it is no longer necessary.

Trading Permit Holder Regulatory Fee

The Fees Schedule provides for a Trading Permit Holder Regulatory Fee of $90 per month, per RTH Trading Permit, applicable to all TPHs, which fee helps more closely cover the costs of regulating all TPHs and performing regulatory responsibilities. In light of the changes to the Exchange's Trading Permit structure, the Exchange proposes to eliminate the TPH Regulatory Fee. The Exchange notes that there is no regulatory requirement to maintain this fee.

[48] As is the case today, the Floor Broker ADV Discount will be available for all Floor Broker Trading Permits held by affiliated Trading Permit Holders and TPH organizations.

[49] In light of the proposal to eliminate the TP Sliding Scales and the Floor Broker rebates currently set forth under Footnote 25, the Exchange proposes to eliminate Footnote 25 in its entirety.

[50] The Exchange notes that subsequent to the Original Filing that proposed these changes on October 1 and 2, 2019 (SR–CBOE–2019–077 and SR–CBOE–2019–082), and subsequent to the Second Proposed Rule Change filing that proposed these changes on November 29, 2019 (SR–CBOE–2019–111), the Exchange amended the proposed Market-Maker Tier Appointment fees to provide that the SPX Tier Appointment Fee will be assessed to any Market-Maker EAP that executes at least 1,000 contracts in SPX (including SPXW) excluding contracts executed during the opening rotation on the final settlement date of VIX options and futures with the expiration used in the VIX settlement calculation in filing No. SR–CBOE–2019–124. The additions proposed by filing SR–CBOE–2019–124 are double underlined in Exhibit 5A and the deletions are doubled bracketed in Exhibit 5A.

[51] Floor Broker Trading Surcharges for SPX/SPXW and VIX are also not changing. The Exchange however, is creating a new table for Floor Broker Trading Surcharges and relocating such fees in the Fees Schedule in connection with the proposal to eliminate fees currently set forth in the ''Trading Permit and Tier Appointment Fees'' Table.

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.[52] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[53] 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,[54] 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[55] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange first stresses that the proposed changes were not designed with the objective to generate an overall increase in access fee revenue, as demonstrated by the anticipated loss of revenue discussed above. Rather, the proposed changes were prompted by the Exchange's technology migration and the adoption of a new (and improved) connectivity infrastructure, rendering the pre-migration structure obsolete. Such changes accordingly necessitated an overhaul of the Exchange's previous access fee structure and corresponding fees. Moreover, the proposed changes more closely aligns the Exchange's access fees to those of its Affiliated Exchanges, and reasonably so, as the Affiliated Exchanges offer substantially similar connectivity and functionality and are on the same platform that the Exchange has now migrated to.

The Exchange also notes that it operates in a highly competitive environment. Indeed, there are currently 16 registered options exchanges that trade options. Based on publicly available information, no single options exchange has more than 23% of the market share.[56] Further, low barriers to entry mean that new exchanges may rapidly and inexpensively enter the market and offer additional substitute platforms to further compete with the Exchange. There is also no regulatory requirement that any market participant connect to any one options exchange, that any market participant connect at a particular connection speed or act in a particular capacity on the Exchange, or trade any particular product offered on an exchange. Moreover, membership is not a requirement to participate on the Exchange. Indeed, the Exchange is unaware of any one options exchange whose membership includes every registered broker-dealer.[57] The rule structure for options exchanges are, in fact, fundamentally different from those of equities exchanges. In particular, options market participants are not forced to connect to (and purchase market data from) all options exchanges. For example, there are many order types that are available in the equities markets that are not utilized in the options markets, which relate to mid-point pricing and pegged pricing which require connection to the SIPs and each of the equities exchanges in order to properly execute those orders in compliance with best execution obligations. Additionally, in the options markets, the linkage routing and trade through protection are handled by the exchanges, not by the individual members. Thus not connecting to an options exchange or disconnecting from an options exchange does not potentially subject a broker-dealer to violate order protection requirements. Gone are the days when the retail brokerage firms (the Fidelity's, the Schwab's, the eTrade's) were members of the options exchanges—they are not members of the Exchange or its affiliates, they do not purchase connectivity to the Exchange, and they do not purchase market data from the Exchange. The Exchange is also not aware of any reason why any particular market participant could not simply drop its connections and cease being a TPH of the Exchange if the Exchange were to establish ''unreasonable'' and uncompetitive price increases for its connectivity alternatives. Indeed, a number of firms currently do not participate on the Exchange, or participate on the Exchange though sponsored access arrangements rather than by becoming a member.

Additionally, the Exchange notes that non-TPHs such as Service Bureaus and Extranets resell Cboe Options connectivity.[58] This indirect connectivity is another viable alternative that is already being used by non-TPHs, which further constrains the price that the Exchange is able to charge for connectivity to its Exchange. Accordingly, in the event that a market participant views one exchange's direct connectivity and access fees as more or less attractive than the competition, they can choose to connect to that exchange indirectly or may choose not to connect to that exchange and connect instead to one or more of the other 15 options markets. For example, two TPHs that connected directly to the Exchange pre-migration, now connect indirectly via an extranet provider. The Exchange notes that it has not received any comments or evidence to suggest the two TPHs that transitioned from direct connections to an indirect connections post-migration were the result of an undue financial burden resulting from the proposed fee changes. Rather, the Exchange believes the transitions demonstrate that indirect connectivity is in fact a viable option for market participants, therefore reflecting a competitive environment.

Additionally, pre-migration, in August 2019, the Exchange had 97 members (TPH organizations), of which nearly half connected indirectly to the Exchange. Similarly, in December 2019, the Exchange had 97 members, of which nearly half of the participants connected indirectly to the Exchange. More specifically, in December 2019, 47 TPHs connected directly to the Exchange and accounted for approximately 66% of the Exchange's volume, 46 TPHs connected indirectly to the Exchange and accounted for approximately 29% of the Exchange's volume and 4 TPHs utilized

[52] 15 U.S.C. 78f(b).

[53] 15 U.S.C. 78f(b)(5).

[54] 15 U.S.C. 78f(b)(4).

[55] 15 U.S.C. 78f(b)(5).

[56] *See* Cboe Global Markets U.S. Options Market Volume Summary (January 27, 2020), available at *https://markets.cboe.com/us/options/market_statistics/*.

[57] The Exchange further notes that even the number of members between the Exchange and its 3 other options exchange affiliates vary.

[58] Prior to migration, there were 13 firms that resold Cboe Options connectivity. Post-migration, the Exchange anticipated that there would be 19 firms that resell Cboe Options connectivity (both physical and logical) and currently there are 15 firms that resell Cboe Options connectivity. The Exchange does not receive any connectivity revenue when connectivity is resold by a third-party, which often is resold to multiple customers, some of whom are agency broker-dealers that have numerous customers of their own. The Exchange does not have specific knowledge as to what latency a market participant may experience using an indirect connection versus a direct connection and notes it may vary by the service provided by the extranet provider and vary between extranet providers. The Exchange believes however, that there are extranet providers able to provide connections with a latency that is comparable to latency experienced using a direct connection.

both direct and indirect connections and accounted for approximately 5% of the Exchange's volume. In December 2019, TPHs that connected directly to the Exchange purchased a collective 179 physical ports (including legacy physical ports), 144 of which were 10 Gb ports and 35 of which were 1 Gb ports.[59] The Exchange notes that of those market participants that do connect to the Exchange, it is the individual needs of each market participant that determine the amount and type of Trading Permits and physical and logical connections to the Exchange.[60] With respect to physical connectivity, many TPHs were able to purchase small quantities of physical ports. For example, approximately 36% of TPHs that connected directly to the Exchange purchased only one to two 1 Gb ports, approximately 40% purchased only one to two 10 Gb ports, and approximately 40% had purchased a combined total of one to two ports (for both 1 Gb and 10 Gb). Further, no TPHs that connected directly to the Exchange had more than five 1 Gb ports, and only 8.5% of TPHs that connected directly to the Exchange had between six and ten 10 GB ports and only 8.5% had between ten and fourteen 10 Gb ports. There were also a combined total of 41 ports used for indirect connectivity (twenty-one 1 Gb ports and twenty 10 Gb ports).[61] The Exchange notes that all types of members connected indirectly to the Exchange including Clearing firms, Floor Brokers, order flow providers, and on-floor and off-floor Market-Makers, further reflecting the fact that each type of market participant has the option to participate on an exchange without direct connectivity. Accordingly, market participants choose if and how to connect to a particular exchange and because it is a choice, the Exchange must set reasonable connectivity pricing, otherwise prospective members would not connect and existing members would disconnect or connect through a third-party reseller of connectivity.

Moreover, the Exchange notes that the Commission itself has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Particularly, 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.'' [62] The number of available exchanges to connect to ensures increased competition in the marketplace, and constrains the ability of exchanges to charge supracompetitive fees for access to its market. The Exchange is also not aware of any evidence that has been offered or demonstrated that a market share of approximately 23% provides the Exchange with anti-competitive pricing power. As discussed, if an exchange sets too high of a fee for connectivity and/or market data services for its relevant marketplace, market participants can choose to disconnect from the Exchange.

The Exchange also believes that competition in the marketplace constrains the ability of exchanges to charge supracompetitive fees for access to its market, even if such market, like the Exchange, offers proprietary products exclusive to that market. Notably, just as there is no regulatory requirement to become a member of any one options exchange, there is also no regulatory requirement for any market participant to trade any particular product, nor is there any requirement that any Exchange create or indefinitely maintain any particular product.[63] The Exchange also highlights that market participants may trade an Exchange's proprietary products through a third-party without directly or indirectly connecting to the Exchange. Additionally, market participants may trade any options product, including proprietary products, in the Over-the-Counter (OTC) markets. Market participants may also access other exchanges to trade other similar or competing proprietary or multi-listed products. Alternative products to the Exchange's proprietary products may include other options products, including options on ETFs or options futures, as well as particular ETFs or futures. For example, singly-listed SPX options may compete with the following products traded on other markets: Multiply-listed SPY options (options on the ETF), E-mini S&P 500 Options (options on futures), and E-Mini S&P 500 futures (futures on index). Other options exchanges are also not precluded from creating new proprietary products that may achieve similar objectives to (and therefore compete with) the Exchange's existing proprietary products. Indeed, even though exclusively-listed proprietary products may not be offered by competitors, a competitor could create similar products if demand were adequate. In connection with a recently proposed amendment to the National Market System Plan Governing the Consolidated Audit Trail (''CAT NMS Plan''),[64] the Commission discussed the existence of competition in the marketplace generally, and particularly for exchanges with unique business models. Specifically, the Commission contemplated the possibility of a forced exit by an exchange as a result of a proposed amendment that could reduce the amount of CAT funding a participant could recover if certain implementation milestones were missed. The Commission acknowledged that, even if an exchange were to exit the marketplace due to its proposed fee-related change, it would not significantly impact competition in the market for exchange trading services because these markets are served by multiple competitors.[65] The Commission explicitly stated that ''[c]onsequently, demand for these services in the event of the exit of a competitor is likely to be swiftly met by existing competitors.'' [66] The Commission further recognized that while some exchanges may have a unique business model that is not currently offered by competitors, a competitor could create similar business models if demand were adequate, and if they did not do so, the Commission believes it would be likely that new entrants would do so if the exchange

[59] Of the 4 TPHs that connected both directly and indirectly to the Exchange, 1 TPH had two 1 Gb Ports and the remaining 3 TPHs had a combined total of six 10 Gb ports.

[60] To assist market participants that are connected or considering connecting to the Exchange, the Exchange provides detailed information and specifications about its available connectivity alternatives in the Cboe C1 Options Exchange Connectivity Manual, as well as the various technical specifications. *See http://markets.cboe.com/us/options/support/technical/.*

[61] The Exchange notes that it does not know how many, and which kind of, connections each TPH that indirectly connects to the Exchange has.

[62] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[63] If an option class is open for trading on another national securities exchange, the Exchange may delist such option class immediately. For proprietary products, the Exchange may determine to not open for trading any additional series in that option class; may restrict series with open interest to closing transactions, provided that, opening transactions by Market-Makers executed to accommodate closing transactions of other market participants and opening transactions by TPH organizations to facilitate the closing transactions of public customers executed as crosses pursuant to and in accordance with Rule 6.74(b) or (d) may be permitted; and may delist the option class when all series within that class have expired. *See* Cboe Rule 4.4, Interpretations and Policies .11.

[64] *See* Securities Exchange Act Release No. 86901 (September 9, 2019), 84 FR 48458 (September 13, 2019) (File No. S7–13–19).

[65] *Id.*

[66] *Id.*

with that unique business model was otherwise profitable.[67] Similarly, although the Exchange may have proprietary products not offered by other competitors, not unlike unique business models, a competitor could create similar products to an existing proprietary product if demand were adequate. As such, the Exchange is still very much subject to competition and does not possess anti-competitive pricing power, even with its offering of proprietary products. Rather, the Exchange must still set reasonable connectivity pricing, otherwise prospective members would not connect, and existing members would disconnect or connect through a third-party reseller of connectivity, regardless of what products its offers.

For all the reasons discussed above and in this filing, the Exchange believes its proposed fees are reasonable as the Exchange was subject to significant competitive forces in setting its proposed fees. In addition, the Exchange believes its proposed fees are reasonable in light of the numerous benefits the new connectivity infrastructure provides market participants. As described, the post-migration connectivity architecture provides for a latency equalized infrastructure, improved system performance, and increased sustained order and quote per second capacity. As such, even where a fee for a particular type or kind of connectivity may be higher than it was to its pre-migration equivalent, such increase is reasonable given the increased benefits market participants are getting for a similar or modestly higher price. The Exchange further believes that the reasonableness of its proposed connectivity fees is demonstrated by the very fact that such fees are in line with, and in some cases lower than, the costs of connectivity at other Exchanges,[68] including its own affiliated exchanges which have the same connectivity infrastructure the Exchange has migrated to.[69]

Furthermore, in determining the proposed fee changes discussed above, the Exchange reviewed the current competitive landscape, considered the fees historically paid by market participants for connectivity to the pre-migration system, and also assessed the impact on market participants to ensure that the proposed fees would not create an undue financial burden on any market participants, including smaller market participants. Indeed, the Exchange received no comments from any TPH suggesting they were unduly burdened by the proposed changes described herein, which were first announced via Exchange Notice nearly two months in advance of the migration, nor were any timely comment letters received by the Commission by the comment period submission deadline of November 12, 2019.[70] The Exchange also underscores the fact that no comment letters were received in response to its Second Proposed Rule Change, and that no market participant has provided any written comments specifically suggesting that the Exchange has failed to provide sufficient information in the Second Proposed Rule Change to meets its burden to demonstrate its proposed fees are consistent with the requirements of the Exchange Act.

The proposed connectivity structure and corresponding fees, like the pre-migration connectivity structure and fees, continues to provide market participants flexibility with respect to how to connect to the Exchange based on each market participants' respective business needs. For example, the amount and type of physical and logical ports are determined by factors relevant and specific to each market participant, including its business model, costs of connectivity, how its business is segmented and allocated and volume of messages sent to the Exchange. Moreover, the Exchange notes that it does not have unlimited system capacity to support an unlimited number of order and quote entry per second. Accordingly, the proposed connectivity fees, and connectivity structure are designed to encourage market participants to be efficient with their respective physical and logical port usage. While the Exchange has no way of predicting with certainty the amount or type of connections market participants will in fact purchase, if any, the Exchange anticipates that like today, some market participants will continue to decline to connect and participate on the Exchange, some will participate on the Exchange via indirect connectivity, some will only purchase one physical connection and/or logical port connection, and others will purchase multiple connections.

In sum, the Exchange believes the proposed fees are reasonable and reflect a competitive environment, as the Exchange seeks to amend its access fees in connection with the migration of its technology platform, while still attracting market participants to continue to be, or become, connected to the Exchange.

Physical Ports

The Exchange believes increasing the fee for the new 10 Gb Physical Port is reasonable because unlike, the current 10 Gb Network Access Ports, the new Physical Ports provides a connection through a latency equalized infrastructure with faster switches and also allows access to both unicast order entry and multicast market data with a single physical connection. As discussed above, legacy Network Access Ports do not permit market participants to receive unicast and multicast connectivity. As such, in order to receive both connectivity types pre-migration, a market participant needed to purchase and maintain at least two 10 Gb Network Access Ports. The proposed Physical Ports not only provide latency equalization (*i.e.,* eliminate latency advantages between market participants based on location) as compared to the legacy ports, but also alleviate the need to pay for two physical ports as a result of needing unicast and multicast connectivity. Accordingly, market participants who historically had to purchase two separate ports for each of multicast and unicast activity, will be able to purchase only one port, and consequently pay lower fees overall. For example, pre-migration if a TPH had two 10 Gb legacy Network Access Ports, one of which received unicast traffic and the other of which received multicast traffic, that TPH would have been assessed $10,000 per month ($5,000 per port). Under the proposed rule change, using the new Physical Ports, that TPH has the option of utilizing one single port, instead of two ports, to receive both unicast and multicast traffic, therefore paying only $7,000 per month for a port that provides both connectivity types. The Exchange notes that pre-migration, approximately 50% of TPHs maintained two or more 10 Gb Network Access Ports. While the Exchange has no way of predicting with certainty the amount

[67] *Id.*

[68] *See e.g.,* Nasdaq PHLX and ISE Rules, General Equity and Options Rules, General 8. Phlx and ISE each charge a monthly fee of $2,500 for each 1Gb connection, $10,000 for each 10Gb connection and $15,000 for each 10Gb Ultra connection. *See also* Nasdaq Price List—Trading Connectivity. Nasdaq charges a monthly fee of $7,500 for each 10Gb direct connection to Nasdaq and $2,500 for each direct connection that supports up to 1Gb. *See also* NYSE American Fee Schedule, Section V.B, and Arca Fees and Charges, Co-Location Fees. NYSE American and Arca each charge a monthly fee of $5,000 for each 1Gb circuit, $14,000 for each 10Gb circuit and $22,000 for each 10Gb LX circuit.

[69] *See e.g.,* Affiliated Exchange Fee Schedules, Physical Connectivity Fees. For example, Cboe BZX, Cboe EDGX and C2 each charge a monthly fee of $2,500 for each 1Gb connection and $7,500 for each 10Gb connection.

[70] *See* Exchange Notice ''Cboe Options Exchange Access and Capacity Fee Schedule Changes Effective October 1, 2019 and November 1, 2019'' Reference ID C2019081900.

or type of connections market participants will in fact purchase post-migration, the Exchange anticipated approximately 50% of the TPHs with two or more 10 Gb Network Access Ports to reduce the number of 10 Gb Physical Ports that they purchase and expected the remaining 50% of TPHs to maintain their current 10 Gb Physical Ports, but reduce the number of 1 Gb Physical Ports. Particularly, pre-migration, a number of TPHs maintained two 10 Gb Network Access Ports to receive multicast data and two 1 Gb Network Access Ports for order entry (unicast connectivity). As the new 10 Gb Physical Ports are able to accommodate unicast connectivity (order entry), TPHs may choose to eliminate their 1 Gb Network Access Ports and utilize the new 10 Gb Physical Ports for both multicast and unicast connectivity. The Exchange notes that many market participants are still transitioning to the new connectivity structure and as such, the Exchange does not expect its projections regarding port purchases to be realized prior to February 2020.

As discussed above, if a TPH deems a particular exchange as charging excessive fees for connectivity, such market participants may opt to terminate their connectivity arrangements with that exchange, and adopt a possible range of alternative strategies, including routing to the applicable exchange through another participant or market center or taking that exchange's data indirectly. Accordingly, if the Exchange charges excessive fees, it would stand to lose not only connectivity revenues but also revenues associated with the execution of orders routed to it, and, to the extent applicable, market data revenues. The Exchange believes that this competitive dynamic imposes powerful restraints on the ability of any exchange to charge unreasonable fees for physical connectivity. The Exchange also notes that the proposal represents an equitable allocation of reasonable dues, fees and other charges as its fees for physical connectivity are reasonably constrained by competitive alternatives, as discussed above. The proposed amounts are in line with, and in some cases lower than, the costs of physical connectivity at other Exchanges,[71] including the Cboe Affiliated Exchanges which have the same connectivity infrastructure the Exchange has migrated to.[72] The Exchange does not believe it is unreasonable to assess fees that are in line with fees that have already been established for the same physical ports used to connect to the same connectivity infrastructure and common platform. The Exchange believes the proposed Physical Port fees are equitable and not unreasonably discriminatory as the connectivity pricing is associated with relative usage of the various market participants and the Exchange has not been presented with any evidence to suggest its proposed fee changes would impose a barrier to entry for participants, including smaller participants. In fact, as noted above, the Exchange is unaware of any market participant that has terminated direct connectivity solely as a result of the proposed fee changes. The Exchange also believes increasing the fee for 10 Gb Physical Ports and charging a higher fee as compared to the 1 Gb Physical Port is equitable as the 1 Gb Physical Port is 1/10th the size of the 10 Gb Physical Port and therefore does not offer access to many of the products and services offered by the Exchange (*e.g.,* ability to receive certain market data products). Thus the value of the 1 Gb alternative is lower than the value of the 10 Gb alternative, when measured based on the type of Exchange access it offers. Moreover, market participants that purchase 10 Gb Physical Ports utilize the most bandwidth and therefore consume the most resources from the network. As such, the Exchange believes the proposed fees for the 1 and 10 Gb Physical Ports, respectively are reasonably and appropriately allocated.

Data Port Fees

The Exchange believes assessing the data port fee per data source, instead of per port, is reasonable because it may allow for market participants to maintain more ports at a lower cost and applies uniformly to all market participants. The Exchange believes the proposed increase is reasonable because, as noted above, market participants may pay lower fees as a result of charging per data source and not per data port. Indeed, while the Exchange has no way of predicting with certainty the impact of the proposed changes, the Exchange had anticipated approximately 76% of the 51 market participants who pay data port fees to pay the same or lower fees upon implementation of the proposed change. Currently, 46 market participants[73] pay the proposed data port fees, of which approximately 78% market participants are paying the same or lower fees in connection with the proposed change. Monthly savings for firms paying lower fees range from $500 to $6,000 per month. The Exchange also anticipated that 19% of TPHs who pay data port fees would pay a modest increase of only $500 per month. To date, approximately 22% market participants pay higher fees, with the majority of those market participants paying a modest monthly increase of $500 and only 3 firms paying either $1,000 or $1,500 more per month. Additionally as discussed above, the Exchange's affiliate C2 has the same fee which is also assessed at the proposed rate and assessed by data source instead of per port. The proposed name change is also appropriate in light of the Exchange's proposed changes and may alleviate potential confusion.

Logical Connectivity

Port Fees

The Exchange believes it's reasonable to eliminate certain fees associated with legacy options for connecting to the Exchange and to replace them with fees associated with new options for connecting to the Exchange that are similar to those offered at its Affiliated Exchanges. In particular, the Exchange believes it's reasonable to no longer assess fees for CMI and FIX Login IDs because the Login IDs were retired and rendered obsolete upon migration and because the Exchange is proposing to replace them with fees associated with the new logical connectivity options. The Exchange believes that it is reasonable to harmonize the Exchange's logical connectivity options and corresponding connectivity fees now that the Exchange is on a common platform as its Affiliated Exchanges. Additionally, the Exchange notes the proposed fees are the same as, or in line with, the fees assessed on its Affiliated Exchanges for similar connectivity.[74] The proposed logical connectivity fees are also equitable and not unfairly

[71] *See e.g.,* Nasdaq PHLX and ISE Rules, General Equity and Options Rules, General 8. Phlx and ISE each charge a monthly fee of $2,500 for each 1Gb connection, $10,000 for each 10Gb connection and $15,000 for each 10Gb Ultra connection. *See also* Nasdaq Price List—Trading Connectivity. Nasdaq charges a monthly fee of $7,500 for each 10Gb direct connection to Nasdaq and $2,500 for each direct connection that supports up to 1Gb. *See also* NYSE American Fee Schedule, Section V.B, and Arca Fees and Charges, Co-Location Fees. NYSE American and Arca each charge a monthly fee of $5,000 for each 1Gb circuit, $14,000 for each 10Gb circuit and $22,000 for each 10Gb LX circuit.

[72] *See e.g.,* Affiliated Exchange Fee Schedules, Physical Connectivity Fees. For example, Cboe BZX, Cboe EDGX and C2 each charge a monthly fee of $2,500 for each 1Gb connection and $7,500 for each 10Gb connection.

[73] The Exchange notes the reduction in market participants that pay the data port fee is due to firm consolidations and acquisitions.

[74] *See* Affiliated Exchange Fee Schedules, Logical Port Fees.

discriminatory because the Exchange will apply the same fees to all market participants that use the same respective connectivity options.

The Exchange believes the proposed Logical Port fees are reasonable as it is the same fee for Drop Ports and the first five BOE/FIX Ports that is assessed for CMI and FIX Logins, which the Exchange is eliminating in lieu of logical ports. Additionally, while the proposed ports will be assessed the same monthly fees as current CMI/FIX Login IDs, the proposed logical ports provide for significantly more message traffic. Specifically, the proposed BOE/FIX Logical Ports will provide for 3 times the amount of quoting [75] capacity and approximately 165 times order entry capacity. Similarly, the Exchange believes the proposed BOE Bulk Port fees are reasonable because while the fees are higher than the CMI and FIX Login Id fees and the proposed Logical Port fees, BOE Bulk Ports offer significantly more bandwidth capacity than both CMI and FIX Login Ids and Logical Ports. Particularly, a single BOE Bulk Port offers 45 times the amount of quoting bandwidth than CMI/FIX Login Ids [76] and 5 times the amount of quoting bandwidth than Logical Ports will offer. Additionally, the Exchange believes that its fees for logical connectivity are reasonable, equitable, and not unfairly discriminatory as they are designed to ensure that firms that use the most capacity pay for that capacity, rather than placing that burden on market participants that have more modest needs. Although the Exchange charges a ''per port'' fee for logical connectivity, it notes that this fee is in effect a capacity fee as each FIX, BOE or BOE Bulk port used for order/quote entry supports a specified capacity (*i.e.,* messages per second) in the matching engine, and firms purchase additional logical ports when they require more capacity due to their business needs.

An obvious driver for a market participant's decision to purchase multiple ports will be their desire to send or receive additional levels of message traffic in some manner, either by increasing their total amount of message capacity available, or by segregating order flow for different trading desks and clients to avoid latency sensitive applications from competing for a single thread of resources. For example, a TPH may purchase one or more ports for its market making business based on the amount of message traffic needed to support that business, and then purchase separate ports for proprietary trading or customer facing businesses so that those businesses have their own distinct connection, allowing the firm to send multiple messages into the Exchange's trading system in parallel rather than sequentially. Some TPHs that provide direct market access to their customers may also choose to purchase separate ports for different clients as a service for latency sensitive customers that desire the lowest possible latency to improve trading performance. Thus, while a smaller TPH that demands more limited message traffic may connect through a service bureau or other service provider, or may choose to purchase one or two logical ports that are billed at a rate of $750 per month each, a larger market participant with a substantial and diversified U.S. options business may opt to purchase additional ports to support both the volume and types of activity that they conduct on the Exchange. While the Exchange has no way of predicting with certainty the amount or type of logical ports market participants will in fact purchase post-migration, the Exchange anticipated approximately 16% of TPHs to purchase one to two logical ports, and approximately 22% of TPHs to not purchase any logical ports. To date, 13% of TPHs purchased one to two logical ports and 27% have not purchased any logical ports. At the same time, market participants that desire more total capacity due to their business needs, or that wish to segregate order flow by purchasing separate capacity allocations to reduce latency or for other operational reasons, would be permitted to choose to purchase such additional capacity at the same marginal cost. The Exchange believes the proposal to assess an additional Logical and BOE Bulk port fee for incremental usage per logical port is reasonable because the proposed fees are modestly higher than the proposed Logical Port and BOE Bulk fees and encourage users to mitigate message traffic as necessary. The Exchange notes one of its Affiliated Exchanges has similar implied port fees.[77]

In sum, the Exchange believes that the proposed BOE/FIX Logical Port and BOE Bulk Port fees are appropriate as these fees would ensure that market participants continue to pay for the amount of capacity that they request, and the market participants that pay the most are the ones that demand the most resources from the Exchange. The Exchange also believes that its logical connectivity fees are aligned with the goals of the Commission in facilitating a competitive market for all firms that trade on the Exchange and of ensuring that critical market infrastructure has ''levels of capacity, integrity, resiliency, availability, and security adequate to maintain their operational capability and promote the maintenance of fair and orderly markets.'' [78]

The Exchange believes waiving the FIX/BOE Logical Port fee for one FIX Logical Port used to access PULSe and Silexx (for FLEX Trading) is reasonable because it will allow all TPHs using PULSe and Silexx to avoid having to pay a fee that they would otherwise have to pay. The waiver is equitable and not unfairly discriminatory because TPHs using PULSe are already subject to a monthly fee for the PULSe Workstation, which the Exchange views as inclusive of fees to access the Exchange. Moreover, while PULSe users today do not require a FIX/CMI Login Id, post-migration, due to changes to the connectivity infrastructure, PULSe users will be required to maintain a FIX Logical Port and as such incur a fee they previously would not have been subject to. Similarly, the Exchange believes that the waiver for Silexx (for FLEX trading) will encourage TPHs to transact business using FLEX Options using the new Silexx System and encourage trading of FLEX Options. Additionally, the Exchange notes that it currently waives the Login Id fees for Login IDs used to access the CFLEX system.

The Exchange believes its proposed fee for Purge Ports is reasonable as it is also in line with the amount assessed for purge ports offered by its Affiliated Exchanges, as well as other exchanges.[79] Moreover, the Exchange believes that offering purge port functionality at the Exchange level promotes robust risk management across the industry, and thereby facilitates investor protection. Some market participants, and, in particular, larger firms, could build similar risk functionality on their trading systems that permit the flexible cancellation of orders entered on the Exchange. Offering Exchange level protections however, ensures that such functionality is widely available to all firms, including smaller firms that may otherwise not be willing to incur the costs and development work necessary

[75] Based on the purchase of a single Market-Maker Trading Permit or Bandwidth Packet.

[76] Based on the purchase of a single Market-Maker Trading Permit or Bandwidth Packet.

[77] *See e.g.,* Cboe C2 Options Exchange Fees Schedule, Logical Connectivity Fees.

[78] *See* Securities Exchange Act Release No. 73639 (November 19, 2014), 79 FR 72251 (December 5, 2014) (File No. S7–01–13) (Regulation SCI Adopting Release).

[79] *See* Affiliated Exchange Fee Schedules, Logical Port Fees. *See also,* Nasdaq ISE Pricing Schedule, Section 7(C). ISE charges a fee of $1,100 per month for SQF Purge Ports.

to support their own customized mass cancel functionality. The Exchange operates in a highly competitive market in which exchanges offer connectivity and related services as a means to facilitate the trading activities of TPHs and other participants. As the proposed Purge Ports provide voluntary risk management functionality, excessive fees would simply serve to reduce demand for this optional product. The Exchange also believes that the proposed Purge Port fees are not unfairly discriminatory because they will apply uniformly to all TPHs that choose to use dedicated Purge Ports. The proposed Purge Ports are completely voluntary and, as they relate solely to optional risk management functionality, no TPH is required or under any regulatory obligation to utilize them. The Exchange believes that adopting separate fees for these ports ensures that the associated costs are borne exclusively by TPHs that determine to use them based on their business needs, including Market-Makers or similarly situated market participants. Similar to Purge Ports, Spin and GRP Ports are optional products that provide an alternative means for market participants to receive multicast data and request and receive a retransmission of such data. As such excessive fees would simply serve to reduce demand for these products, which TPHs are under no regulatory obligation to utilize. All TPHs that voluntarily select these service options (*i.e.,* Purge Ports, Spin Ports or GRP Ports) will be charged the same amount for the same respective services. All TPHs have the option to select any connectivity option, and there is no differentiation among TPHs with regard to the fees charged for the services offered by the Exchange.

Access Credits

The Exchange believes the proposal to adopt credits for BOE Bulk Ports is reasonable, equitable and not unfairly discriminatory because it provides an opportunity for TPHs to pay lower fees for logical connectivity. The Exchange notes that the proposed credits are in lieu of the current credits that Market-Makers are eligible to receive today for Trading Permits fees. Although only Market-Makers may receive the proposed BOE Bulk Port credits, Market-Makers are valuable market participants that provide liquidity in the marketplace and incur costs that other market participants do not incur. For example, Market-Makers have a number of obligations, including quoting obligations and fees associated with appointments that other market participants do not have. The Exchange also believes that the proposals provide incremental incentives for TPHs to strive for the higher tier levels, which provide increasingly higher benefits for satisfying increasingly more stringent criteria, including criteria to provide more liquidity to the Exchange. The Exchange believes the value of the proposed credits is commensurate with the difficulty to achieve the corresponding tier thresholds of each program.

First, the Exchange believes the proposed BOE Bulk Port fee credits provided under AVP will incentivize the routing of orders to the Exchange by TPHs that have both Market-Maker and agency operations, as well as incent Market-Makers to continue to provide critical liquidity notwithstanding the costs incurred with being a Market-Maker. More specifically, in the options industry, many options orders are routed by consolidators, which are firms that have both order router and Market-Maker operations. The Exchange is aware not only of the importance of providing credits on the order routing side in order to encourage the submission of orders, but also of the operations costs on the Market-Maker side. The Exchange believes the proposed change to AVP continues to allow the Exchange to provide relief to the Market-Maker side via the credits, albeit credits on BOE Bulk Port fees instead of Trading Permit fees. Additionally, the proposed credits may incentivize and attract more volume and liquidity to the Exchange, which will benefit all Exchange participants through increased opportunities to trade as well as enhancing price discovery. While the Exchange has no way of predicting with certainty how many and which TPHs will satisfy the required criteria to receive the credits, the Exchange had anticipated approximately two TPHs (out of approximately 5 TPHs that are eligible for AVP) to reach VIP Tiers 4 or 5 and consequently earn the BOE Bulk Port fee credits for their respective Market-Maker affiliate. For the month of October 2019, two TPHs received access credits under Tier 5 and no TPHs received credits under Tier 4. The Exchange notes that it believes its reasonable, equitable and not unfairly discriminatory to no longer provider access credits for Market-Makers whose affiliates achieve VIP Tiers 2 or 3 as the Exchange has adopted another opportunity for all Market-Makers, not just Market-Makers that are part of a consolidator, to receive credits on BOE Bulk Port fees (*i.e.,* credits available via the proposed Market-Maker Access Credit Program). More specifically, limiting the credits under AVP to the top two tiers enables the Exchange to provide further credits under the new Market-Maker Access Credit Program. Furthermore, the Exchange notes that it is not required to provide any credits at any tier level.

The Exchange believes the proposed BOE Bulk Port fee credits available for TPHs that reach certain Performance Tiers under the Liquidity Provider Sliding Scale Adjustment Table is reasonable as the credits provide for reduced connectivity costs for those Market-Makers that reach the required thresholds. The Exchange believe it's reasonable, equitable and not unfairly discriminatory to provide credits to those Market-Makers that primarily provide and post liquidity to the Exchange, as the Exchange wants to continue to encourage Market-Makers with significant Make Rates to continue to participate on the Exchange and add liquidity. Greater liquidity benefits all market participants by providing more trading opportunities and tighter spreads.

Moreover, the Exchange notes that Market-Makers with a high Make Rate percentage generally require higher amounts of capacity than other Market-Makers. Particularly, Market-Makers with high Make Rates are generally streaming significantly more quotes than those with lower Make Rates. As such, Market-Makers with high Make Rates may incur more costs than other Market-Makers as they may need to purchase multiple BOE Bulk Ports in order to accommodate their capacity needs. The Exchange believes the proposed credits for BOE Bulk Ports encourages Market-Makers to continue to provide liquidity for the Exchange, notwithstanding the costs incurred by purchasing multiple ports. Particularly, the proposal is intended to mitigate the costs incurred by traditional Market-Makers that focus on adding liquidity to the Exchange (as opposed to those that provide and take, or just take). While the Exchange cannot predict with certainty which Market-Makers will reach Performance Tiers 4 and 5 each month, based on historical performance it anticipated approximately 10 Market-Makers would achieve Tiers 4 or 5. In October 2019, 12 Market-Makers achieved Tiers 4 or 5. Lastly, the Exchange notes that it is common practice among options exchanges to differentiate fees for adding liquidity and fees for removing liquidity.[80]

[80] *See e.g.,* MIAX Options Fees Schedule, Section 1(a), Market Maker Transaction Fees.

Bandwidth Packets and CMI CAS Server Fees

The Exchange believes it's reasonable to eliminate Bandwidth Packet fees and the CMI CAS Server fee because TPHs will not pay fees for these connectivity options and because Bandwidth Packets and CAS Servers have been retired and rendered obsolete as part of the migration. The Exchange believes that even though it will be discontinuing Bandwidth Packets, the proposed incremental pricing for Logical Ports and BOE Bulk Ports will continue to encourage users to mitigate message traffic. The proposed change is equitable and not unfairly discriminatory because it will apply uniformly to all TPHs.

Access Fees

The Exchange believes the restructuring of its Trading Permits is reasonable in light of the changes to the Exchange's connectivity infrastructure in connection with the migration and the resulting separation of bandwidth allowance, logins and appointment costs from each Trading Permit. The Exchange also believes that it is reasonable to harmonize the Exchange's Trading Permit structure and corresponding connectivity options to more closely align with the structures offered at its Affiliated Exchanges once the Exchange is on a common platform as its Affiliated Exchanges.[81] The proposed Trading Permit structure and corresponding fees are also in line with the structure and fees provided by other exchanges. The proposed Trading Permit fees are also equitable and not unfairly discriminatory because the Exchange will apply the same fees to all market participants that use the same type and number of Trading Permits.

With respect to electronic Trading Permits, the Exchange notes that TPHs previously requested multiple Trading Permits because of bandwidth, login or appointment cost needs. As described above, in connection with migration, bandwidth, logins and appointment costs are no longer tied to Trading Permits or Bandwidth Packets and as such, the need to hold multiple permits and/or Bandwidth Packets is obsolete. As such, the Exchange believes the structure to require only one of each type of applicable electronic Trading Permit is appropriate. Moreover, the Exchange believes offering separate marketing making permits for off-floor and on-floor Market-Makers provides for a cleaner, more streamlined approach to trading permits and corresponding fees. Other exchanges similarly provide separate and distinct fees for Market-Makers that operate on-floor vs off-floor and their corresponding fees are similar to those proposed by the Exchange.[82]

The Exchange believes the proposed fee for its MM EAP Trading Permits is reasonable as it is the same fee it assess today for Market-Maker Trading Permits (*i.e.,* $5,000 per month per permit). Additionally, the proposed fee is in line with, and in some cases even lower than, the amounts assessed for similar access fees at other exchanges, including its affiliate C2.[83] The Exchange believes the proposed EAP fee is also reasonable, and in line with the fees assessed by other Exchanges for non-Market-Maker electronic access.[84] The Exchange notes that while the Trading Permit fee is increasing, TPHs overall cost to access the Exchange may be reduced in light of the fact that a TPH no longer must purchase multiple Trading Permits, Bandwidth Packets and Login Ids in order to receive sufficient bandwidth and logins to meet their respective business needs. To illustrate the value of the new connectivity infrastructure, the Exchange notes that the cost that would be incurred by a TPH today in order to receive the same amount of order capacity that will be provided by a single Logical Port post-migration (*i.e.,* 5,000 orders per second), is approximately 98% higher than the cost for the same capacity post-migration. The following examples further demonstrate potential cost savings/value added for an EAP holder with modest capacity needs and an EAP holder with larger capacity needs:

TPH THAT HOLDS 1 EAP, NO BANDWIDTH PACKETS AND 1 CMI LOGIN

	Current fee structure	Post-migration fee structure
EAP	$1,600	$3,000.
CMI Login/Logical Port	$750	$750.
Bandwidth Packets	0	N/A.
Total Bandwidth Available	30 orders/sec	5,000 orders/sec.
Total Cost	$2,350	$3,750.
Total Cost per message	$78.33/order/sec	$0.75/order/sec.

TPH THAT HOLDS 1 EAP, 4 BANDWIDTH PACKETS AND 15 CMI LOGINS

	Current fee structure	Post-migration fee structure
EAP	$1,600	$3,000.
CMI Login/Logical Port	$11,250 (15@750)	$750.
Bandwidth Packets	$6,400 (4@$1,600)	N/A.
Total Bandwidth Available	150 orders/sec	5,000 orders/sec.
Total Cost	$19,250	$3,750.
Total Cost per message	$128.33/order/sec	$0.75/order/sec.

[81] For example, the Exchange's affiliate, C2, similarly provides for Trading Permits that are not tied to connectivity, and similar physical and logical port options at similar pricings. *See* Cboe C2 Options Exchange Fees Schedule. Physical connectivity and logical connectivity are also not tied to any type of permits on the Exchange's other options exchange affiliates.

[82] *See e.g.,* PHLX Section 8A, Permit and Registration Fees. *See also,* BOX Options Fee Schedule, Section IX Participant Fees; NYSE American Options Fees Schedule, Section III(A) Monthly ATP Fees and NYSE Arca Options Fees and Charges, OTP Trading Participant Rights. For similar Trading Floor Permits for Floor Market Makers, Nasdaq PHLX charges $6,000; BOX charges up to $5,500 for 3 registered permits in addition to a $1,500 Participant Fee, NYSE Arca charges up to $6,000; and NYSE American charges up to $8,000.

[83] *See e.g.,* Cboe C2 Options Exchange Fees Schedule. *See also,* NYSE Arca Options Fees and Charges, General Options and Trading Permit (OTP) Fees, which assesses up to $6,000 per Market Maker OTP and NYSE American Options Fee Schedule, Section III. Monthly ATP Fees, which assess up to $8,000 per Market Maker ATP. *See also,* PHLX Section 8A, Permit and Registration Fees, which assesses up to $4,000 per Market Maker Permit.

[84] *See e.g.,* PHLX Section 8A, Permit and Registration Fees, which assesses up to $4,000 per Permit for all member and member organizations other than Floor Specialists and Market Makers.

The Exchange believes the proposal to adopt a new Clearing TPH Permit is reasonable because it offers TPHs that only clear transactions of TPHs a discount. Particularly, Clearing TPHs that also submit orders electronically to the Exchange would purchase the proposed EAP at $3,000 per permit. The Exchange believe it's reasonable to provide a discount to Clearing TPHs that only clear transactions and do not otherwise submit electronic orders to the Exchange. The Exchange notes that another exchange similarly charges a separate fee for clearing firms.[85]

The Exchange believes the proposed fee structure for on-floor Market-Makers is reasonable as the fees are in line with those offered at other Exchanges.[86] The Exchange believes that the proposed fee for MM Floor Permits as compared to MM EAPs is reasonable because it is only modestly higher than MM EAPs and Floor MMs don't have other costs that MM EAP holders have, such as MM EAP Appointment fees.

The Exchange believes its proposed fees for Floor Broker Permits are reasonable because the fees are similar to, and in some cases lower than, the fees the Exchange currently assesses for such permits. Specifically, based on the number of Trading Permits TPHs held upon migration, 60% of TPHs that hold Floor Broker Trading Permits will pay lower Trading Permit fees. Particularly, any Floor Broker holding ten or less Floor Broker Trading Permits will pay lower fees under the proposed tiers as compared to what they pay today. While the remaining 40% of TPHs holding Floor Broker Trading Permits (who each hold between 12–21 Floor Broker Trading Permits) will pay higher fees, the Exchange notes the monthly increase is de minimis, ranging from an increase of 0.6%–2.72%.[87]

The Exchange believes the proposed ADV Discount is reasonable because it provides an opportunity for Floor Brokers to pay lower FB Trading Permit fees, similar to the current rebate program offered to Floor Brokers. The Exchange notes that while the new ADV Discount program includes only customer volume (''C'' origin code) as compared to Customer and Professional Customer/Voluntary Professional, the amount of Professional Customer/Voluntary Professional volume was de minimis and the Exchange does not believe the absence of such volume will have a significant impact.[88] Additionally, the Exchange notes that while the ADV requirements under the proposed ADV Discount program are higher than are required under the current rebate program, the proposed ADV Discount counts volume from all products towards the thresholds as compared to the current rebate program which excludes volume from Underlying Symbol List A (except RLG, RLV, RUI, and UKXM), DJX, XSP, and subcabinet trades. Moreover, the ADV Discount is designed to encourage the execution of orders in all classes via open outcry, which may increase volume, which would benefit all market participants (including Floor Brokers who do not hit the ADV thresholds) trading via open outcry (and indeed, this increased volume could make it possible for some Floor Brokers to hit the ADV thresholds). The Exchange believes the proposed discounts are equitable and not unfairly discriminatory because all Floor Brokers are eligible. While the Exchange has no way of predicting with certainty how many and which TPHs will satisfy the various thresholds under the ADV Discount, the Exchange anticipated approximately 3 Floor Brokers to receive a rebate under the program. To date, 2 Floor Brokers have received a rebate under the program.

The Exchange believes its proposed MM EAP Appointment fees are reasonable in light of the Exchange's elimination of appointment costs tied to Trading Permits. Other exchanges also offer a similar structure with respect to fees for appointment classes.[89] Additionally, the proposed MM EAP Appointment fee structure results in approximately 36% electronic MMs paying lower fees for trading permit and appointment costs. For example, in order to have the ability to make electronic markets in every class on the Exchange, a Market-Maker would need 1 Market-Maker Trading Permit and 37 Appointment Units post-migration. Under, the current pricing structure, in order for a Market-Maker to quote the entire universe of available classes, a Market-Maker would need 33 Appointment Credits, thus necessitating 33 Market-Maker Trading Permits. With respect to fees for Trading Permits and Appointment Unit Fees, under the proposed pricing structure, the cost for a TPH wishing to quote the entire universe of available classes is approximately 29% less (if they are not eligible for the MM TP Sliding Scale) or approximately 2% less (if they are eligible for the MM TP Sliding Scale). To further demonstrate the potential cost savings/value added, the Exchange is providing the following examples comparing current Market-Maker connectivity and access fees to projected connectivity and access fees for different scenarios. The Exchange notes that the below examples not only compare Trading Permit and Appointment Unit costs, but also the cost incurred for logical connectivity and bandwidth. Particularly, the first example demonstrates the total minimum cost that would be incurred today in order for a Market-Maker to have the same amount of capacity as a Market-Maker post-migration that would have only 1 MM EAP and 1 Logical Port (*i.e.,* 15,000 quotes/3 sec). The Exchange is also providing examples that demonstrate the costs of (i) a Market-Maker with small capacity needs and appointment unit of 1.0 and (ii) a Market-Maker with large capacity needs and appointment cost/unit of 30.0:

MARKET-MAKER THAT NEEDS CAPACITY OF 15,000/QUOTES/3 SECONDS

	Current fee structure	Post-migration fee structure
MM Permit/MM EAP	$5,000	$5,000.
Appointment Unit Cost	N/A (1 appointment cost)	$0 (1 appointment unit).
CMI Login/Logical Port	$750[90]	$750.
Bandwidth Packets	$5,500 (2@$2,750)	N/A.
Total Bandwidth Available	15,000 quotes/3 sec	15,000 quotes/3 sec.
Total Cost	$11,250	$5,750.

[85] *See e.g.,* NYSE Arca Options Fees and Charges, General Options and Trading Permit (OTP) Fees and NYSE American Options Fee Schedule, Section III. Monthly ATP Fees.

[86] *See e.g.,* PHLX Section 8A, Permit and Registration Fees, which assesses $6,000 per permit for Floor Specialists and Market Makers.

[87] The Floor Brokers whose fees are increasing have each committed to a minimum number of permits and therefore currently receive the rates set forth in the current Floor Broker TP Sliding Scale.

[88] Furthermore, post-migration the Exchange will not have Voluntary Professionals.

[89] *See e.g.,* PHLX Section 8. Membership Fees, B, Streaming Quote Trader (''SQT'') Fees and C. Remote Market Maker Organization (RMO) Fee.

[90] The maximum quoting bandwidth that may be applied to a single Login Id is 80,000 quotes/3 sec.

MARKET-MAKER THAT NEEDS CAPACITY OF 15,000/QUOTES/3 SECONDS—Continued

	Current fee structure	Post-migration fee structure
Total Cost per message allowed	$0.75/quote/3 sec	$0.38/quote/3 sec.

MARKET MAKER THAT NEEDS CAPACITY OF NO MORE THAN 5,000 QUOTES/3 SECS

	Current fee structure	Post-migration fee structure
MM Permit/MM EAP	$5,000	$5,000.
Appointment Unit Cost	N/A (1 appointment cost)	$0 (1 appointment unit).
CMI Login/Logical Port	$750	$750.
Bandwidth Packets	0	N/A.
Total Bandwidth Available	5,000 quotes/3 sec	15,000 quotes/3 sec.
Total Cost	$5,750	$5,750.
Total Cost per message allowed	$1.15/quote/3 sec	$0.38/quote/3 sec.

MARKET-MAKER THAT NEEDS 30 APPOINTMENT UNITS AND CAPACITY OF 300,000 QUOTES/3 SEC

	Current fee structure	Post-migration fee structure
MM Permits/MM EAP	$105,000 (30 MM Permits assumes eligible for MM TP Sliding Scale) [91].	$5,000.
Appointment Units Cost	N/A (30 appointment costs)	$95,500 (30 appointment units).
CMI Logins/BOE Bulk Port	$3,000 (4@$750) [92]	$3,000 (2 BOE Bulk@$1,500).
Bandwidth Packets	$82,500 (30@$2750)	N/A.
Total Bandwidth Available	300,000 quotes/3 sec	450,000 quotes/3 sec.*
Total Cost	$190,500	$103,500.
Total Cost per message allowed	$0.63/quotes/3 sec	$0.23/quote/3 sec.

* Possible performance degradation at 15,000 messages per second.

The Exchange believes its proposal to provide separate fees for Tier Appointments for MM EAPs and MM Floor Permits as the Exchange will be issuing separate Trading Permits for on-floor and off-floor market making as discussed above. The proposal to eliminate the volume threshold for the electronic SPX Tier Appointment fee is reasonable as no TPHs in the past several months have electronically traded more than 1 SPX contract or less than 100 SPX contracts per month and therefore will not be negatively impacted by the proposed change, and because it aligns the electronic SPX Tier Appointment with the floor SPX Tier Appointment, which has no volume threshold. The Exchange believes the proposal to increase the electronic volume thresholds for VIX and RUT are reasonable as those that do not regularly trade VIX or RUT in open-outcry will continue to not be assessed the fee. In fact, any TPH that executes more than 100 contracts but less than 1,000 in the respective classes will no longer have to pay the proposed Tier Appointment fee. As noted above, the Exchange is not proposing to change the amounts assessed for each Tier Appointment Fee. The proposed change is equitable and not unfairly discriminatory because it will apply uniformly to all TPHs.

Trading Permit Holder Regulatory Fee

The Exchange believes it's reasonable to eliminate the Trading Permit Holder Regulatory fee because TPHs will not pay this fee and because the Exchange is restructuring its Trading Permit structure. The Exchange notes that although it will less closely be covering the costs of regulating all TPHs and performing its regulatory responsibilities, it still has sufficient funds to do so. The proposed change is equitable and not unfairly discriminatory because it will apply uniformly to all TPHs.

The Exchange believes corresponding changes to eliminate obsolete language in connection with the proposed changes described above and to relocate and reorganize its fees in connection with the proposed changes maintain clarity in the Fees Schedule and alleviate potential confusion, thereby removing impediments to and perfecting the mechanism of a free and open market and a national market system, and, in general, protecting investors and the public interest.

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.

With respect to intra-market competition, the Exchange does not believe that the proposed rule change would place certain market participants at the Exchange at a relative disadvantage compared to other market participants or affect the ability of such market participants to compete. As stated above, the Exchange does not believe its proposed pricing will impose a barrier to entry to smaller participants and notes that its proposed connectivity pricing is associated with relative usage of the various market participants. For example, market participants with modest capacity needs can buy the less expensive 1 Gb Physical Port and utilize only one Logical Port. Moreover, the pricing for 1 Gb Physical Ports and FIX/BOE Logical Ports are no different than are assessed today (*i.e.,* $1,500 and $750 per port, respectively), yet the capacity and access associated with each is greatly increasing. While pricing may be increased for larger capacity physical and logical ports, such options provide far more capacity and are purchased by those that consume more resources from the network. Accordingly, the proposed

[91] For simplicity of the comparison, this assumes no appointments in SPX, VIX, RUT, XEO or OEX (which are not included in the TP Sliding Scale).

[92] Given the bandwidth limit per Login Id of 80,000 quotes/3 sec, example assumes Market-Maker purchases minimum amount of Login IDs to accommodate 300,000 quotes/3 sec.

connectivity fees do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation reflects the network resources consumed by the various size of market participants—lowest bandwidth consuming members pay the least, and highest bandwidth consuming members pays the most, particularly since higher bandwidth consumption translates to higher costs to the Exchange.

The Exchange also does not believe that the proposed rule change will result in any burden on inter-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. As discussed in the Statutory Basis section above, options market participants are not forced to connect to (or purchase market data from) all options exchanges, as shown by the number of TPHs at Cboe and shown by the fact that there are varying number of members across each of Cboe's Affiliated Exchanges. The Exchange operates in a highly competitive environment, and its ability to price access and connectivity is constrained by competition among exchanges and third parties. As discussed, there are other options markets of which market participants may connect to trade options. There is also a possible range of alternative strategies, including routing to the exchange through another participant or market center or taking the exchange's data indirectly. For example, there are 15 other U.S. options exchanges, which the Exchange must consider in its pricing discipline in order to compete for market participants. In this competitive environment, market participants are free to choose which competing exchange or reseller to use to satisfy their business needs. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges. 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 written 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 [93] and paragraph (f) of Rule 19b–4 [94] 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–2020–005 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–2020–005. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2020–005, and should be submitted on or before March 10, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[95]

J. Matthew DeLesDernier,

Assistant Secretary.

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[93] 15 U.S.C. 78s(b)(3)(A).

[94] 17 CFR 240.19b–4(f).

[95] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88174; File No. SR–BX–2020–001]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Remove Listing Rule and Other Amendments

February 11, 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 January 29, 2020, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Options 1, Section 1 (Definitions), Options 2, Section 4 (Obligations of Market Makers and Lead Market Makers), Section 5 (Market Maker Quotations), Options 3, Section 2 (Units of Trading and Meaning if Premium Quotes and Orders), Options 3, Section 3 (Minimum Increments), Options 3, Section 8 (Opening and Halt Cross), Options 3, Section 19 (Mass Cancellation of Trading Interest), Options 4, Section 5 (Series of Options

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Contracts Open for Trading), Options 4A, Section 12 (Terms of Index Options Contracts), Options 5, Section 2 (Order Protection) and Options 7 (Pricing Schedule). The Exchange also proposes to relocate current rule text to new Options 2, Section 6 entitled ''Market Maker Orders'' and reserve various sections of the Rulebook.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqbx.cchwallstreet.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 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 Options 1, Section 1 (Definitions), Options 2, Section 4 (Obligations of Market Makers and Lead Market Makers), Section 5 (Market Maker Quotations), Options 3, Section 2 (Units of Trading and Meaning if Premium Quotes and Orders), Options 3, Section 3 (Minimum Increments), Options 3, Section 8 (Opening and Halt Cross), Options 3, Section 19 (Mass Cancellation of Trading Interest), Options 4, Section 5 (Series of Options Contracts Open for Trading), Options 4A, Section 12 (Terms of Index Options Contracts), Options 5, Section 2 (Order Protection) and Options 7 (Pricing Schedule). The Exchange also proposes to relocate current rule text to new Options 2, Section 6 entitled ''Market Maker Orders'' and reserve various sections of the Rulebook. Each change is described below.

Rulebook Harmonization

The Exchange recently harmonized its Rulebook in connection with other Nasdaq affiliated markets. The Exchange proposes to reserve certain rules within the BX Rulebook to represent the presence of rules in similar locations in other Nasdaq affiliated Rulebooks (*e.g.* Nasdaq Phlx LLC).[3]

The Exchange proposes to reserve Sections 17–22 within General 2, Organization and Administration. The Exchange proposes to reserve Sections 11–14 within Options 2, Options Market Participants. The Exchange proposes to reserve Sections 17–21 within Options 4A, Options Index Rules. The Exchange proposes to reserve new section Options 4B. The Exchange proposes to reserve Sections 8–13 within Options 6, Options Trade Administration. The Exchange proposes to reserve Section 7 within Options 6C, Margins. The Exchange proposes to reserve Section 24 within Options 9, Business Conduct.

Definitions

The Exchange proposes to add the definition of an ''Away Best Bid or Offer'' or ''ABBO'' within Options 1, Section 1(a)(1). This term is utilized throughout the Rulebook. Defining this term will bring greater transparency to the Rulebook. The Exchange proposes to renumber the remaining definitions and also update corresponding cross-references within Options 7, Section 1.

The Exchange proposes to remove the terms ''System Book Feed'' and ''System Securities'' from the Options 1, Section 1. The term ''System Book Feed'' is not utilized in the Rulebook currently. The term ''System Securities'' is only utilized within the definition of the term ''System'' at current Options 1, Section 1(a)(58) and within Options 3, Section 8, Opening and Halt Cross.'' The term is simply replaced by referring to option series. The Exchange believes that replacing the term with the term ''option series'' will make the Rulebook clear and remove an unnecessary definition.

Finally, the Exchange is removing the phrase '', or the United States dollar'' from the definition of ''foreign currency'' within current Options 1, Section 1(a)(26). This reference is not needed in this string cite because the United States dollar is a medium of exchange as noted in the introductory phrase to the string cite.

Relocation of Options 2 Rules

The Exchange proposes to relocate Options 2, Section 4(d) and Section 5(e) to Options 2, Section 6, which is currently reserved. Specifically, the Exchange proposes to relocate these sections into Options 6(a) and (b), respectively. Proposed Options 2, Section 6 would be titled ''Market Maker Orders.'' This relocation will harmonize the location of these rules to other Nasdaq affiliated markets.

Removal of Various Listings

Mini Options

The Exchange has not listed Mini Options in several years and is proposing to delete its listing rules and other ancillary trading rules related to the listing of Mini Options. The Exchange notes that it has no open interest in Mini Options.

Specifically, the Exchange proposes to amend Options 3, Section 2 (Units of Trading and Meaning of Premium Quotes and Orders), Options 3, Section 3 (Minimum Increments), Options 4, and Section 5 (Series of Options Contracts Open for Trading) at Supplementary Material .15) to remove references to the handling of Mini Options in the System.

In the event that the Exchange desires to list Mini Options in the future, it would file a rule change with the Commission to adopt rules to list Mini Options.

U.S. Dollar-Settled Foreign Currency Options

The Exchange has not listed U.S. Dollar-Settled Foreign Currency Options (''FCOs'') in several years and is proposing to delete its listing rules and other ancillary trading rules related to the listing of FCOs. The Exchange notes that it has no open interest in FCOs.

Specifically, the Exchange proposes to amend Supplementary Material .16 to Options 4, Section 5 (Series of Options Contracts Open for Trading) to remove references to the handling of FCOs in the System.

In the event that the Exchange desires to list FCOs in the future, it would file a rule change with the Commission to adopt rules to list FCOs.

Mini-Nasdaq-100 Index

The Exchange has not listed Mini-Nasdaq-100 Index options or ''MNX'' or ''Mini-NDX'' in several years and is proposing to delete its listing rules and other ancillary trading rules related to the listing of Mini-Nasdaq-100 Index options. The Exchange notes that it has no open interest in Mini-Nasdaq-100 Index options.

Specifically, the Exchange proposes to amend Supplementary Material .05 to Options 4, Section 5 (Series of Options Contracts Open for Trading) to remove references to the handling of Mini-Nasdaq-100 Index options in the System.

In the event that the Exchange desires to list Mini-Nasdaq-100 Index options in the future, it would file a rule change

[3] *See* SR–Phlx–2020–03 (not yet published).

with the Commission to adopt rules to list Mini-Nasdaq-100 Index options.

Minimum Increments

The Exchange proposes to amend Options 3, Section 3 to relocate Section 3(a)(3) into a new Supplementary Material .01 and title the section, ''Penny Pilot Program.'' The Exchange also proposes to amend a typographical error in Options 3, Section 3(a)(3) to replace ''QQQQs'' with ''QQQs.'' The other changes relate to the removal of Mini Options as explained herein.

Mass Cancellation of Trading Interest

The Exchange proposes to amend the description of Options 3, Section 19 titled ''Mass Cancellation of Trading Interest.'' The proposed amended rule would state, ''An Options Participant may cancel any bids, offers, and orders in any series of options by requesting BX Market Operations [4] staff to effect such cancellation as per the instructions of the Options Participant.'' The Exchange is not amending the System with respect to this rule change. The proposed amended language merely makes clear that an Options Participant may contact BX Market Operations and request the Exchange to cancel any bid, offer or order in any series of options. This is a voluntary service that is offered to market participants. The Exchange, would cancel such bid, offer or order pursuant to the Member's instruction. This amendment would conform the BX rule text to rules of other Nasdaq affiliated markets.[5]

Other Amendments

The Exchange proposes to correct a rule citation within Options 3, Section 4 to risk protections. The Exchange proposes to correct a typographical error notes within Options 4A, Section 12. Specifically, the reference to Options 4, Section 6 should have referenced Options 4, Section 5 instead. The Exchange proposes to remove a reference to paragraph (c) within Options 5, Section 2, as there is no paragraph (c) within the Rule. The Exchange also proposes to update rulebook citations within Options 7, Pricing Schedule to reflect the proposed changes to Options 1, Section 1, Definitions.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[6] in general, and furthers the objectives of Section 6(b)(5) of the Act,[7] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

Rulebook Harmonization

The Exchange's proposal to reserve various sections of the Rules in order to harmonize its Rulebook with other Nasdaq affiliated markets is not a substantive amendment.

Definitions

The Exchange's proposal to add the definition of an ''Away Best Bid or Offer'' or ''ABBO'' within Options 1, Section 1(a)(1) is consistent with the Act because these amendments will add transparency to the Rulebook. The Exchange's proposal to remove the terms ''System Book Feed'' and ''System Securities'' from the Options 1, Section 1 is also consistent with the Act. The term ''System Book Feed'' is not utilized in the Rulebook currently and therefore this term does not need to be defined. The term ''System Securities'' is only utilized within the definition of the term ''System'' at Options 1, Section 1(a)(58) and within Options 3, Section 8, Opening and Halt Cross.'' Replacing the term with the term ''option series'' will make the Rulebook clear.

Relocation of Options 2 Rules

The proposal to relocate Options 2, Section 4(d), which is being reserved, and Section 5(e) to Section 6, which is currently reserved, into Options 6(a) and (b), respectively is consistent with the Act. This amendment is not substantive.

Removal of Various Listings

Mini Options

The Exchange's proposal to removal references to the listing and handling of Mini Options is consistent with the Act because Mini Options have not been listed in several years. Also, the Exchange notes that it has no open interest in Mini Options. In the event that the Exchange desires to list Mini Options in the future, it would file a rule change with the Commission to adopt rules to list Mini Options.

U.S. Dollar-Settled Foreign Currency Options

The Exchange's proposal to removal references to the listing and handling of FCOs is consistent with the Act because FCOs have not been listed in several years. Also, the Exchange notes that it has no open interest in FCOs. In the event that the Exchange desires to list FCOs in the future, it would file a rule change with the Commission to adopt rules to list FCOs.

Mini-Nasdaq-100 Index

The Exchange's proposal to removal references to the listing and handling Mini-Nasdaq-100 Index options is consistent with the Act because Mini-Nasdaq-100 Index options have not been listed in several years. Also, the Exchange notes that it has no open interest in Mini-Nasdaq-100 Index options.

In the event that the Exchange desires to list Mini-Nasdaq-100 Index options in the future, it would file a rule change with the Commission to adopt rules to list Mini-Nasdaq-100 Index options.

Minimum Increments

The Exchange's proposal to relocate parts of Options 3, Section 3 into a new Supplementary Material .01 and add a title for the Penny Pilot Program is consistent with the Act. This amendment will bring greater transparency to the Exchange's Rules.

Mass Cancellation of Trading Interest

The Exchange's proposal to amend the rule text of Mass Cancellation of Trading Interest rule within Options 3, Section 19 is consistent with the Act because the Exchange desires to conform the rule text to other Nasdaq affiliated markets.[8] Permitting Participants to contact Market Operations as a manual alternative to automated functionality, which similarly allows Participants to cancel interest, provides Participants experiencing their own system issues with a means to manage risk. Today, Participants are able to cancel interest, in an automated fashion through protocols [9] and the Kill Switch.[10] This is a voluntary service offered to all Participants.

This amended rule reflects the Exchange's current practice of allowing Participants to contact BX Market Operations and request the Exchange to cancel any bid, offer or order in any series of options. The Exchange would continue to permit Participants to contact market operations and manually request cancellation of interest. The proposed amended language will make

[4] The request to Market Operations is a manual request which is made telephonically.

[5] *See* Nasdaq Phlx LLC (''Phlx'') Nasdaq ISE, LLC (''ISE''), Nasdaq GEMX, LLC (''GEMX'') and Nasdaq MRX, LLC (''MRX'') Options 3, Section 19.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *See* note 5 above.

[9] *See* Options 3 at Supplementary Material .03 to Section 7.

[10] *See* Options 3, Section 17.

clear that an Options Participant may contact BX Market Operations and request the Exchange to cancel any bid, offer or order in any series of options. The Exchange would continue to cancel such bid, offer or order pursuant to the Participant's instruction.

This service, which permits Participants to cancel interest, does not diminish a Market Maker's obligation with respect to providing two-sided quotations and this rule is not inconsistent with other firm quote obligations of the Market Maker. Upon the request of a Participant, BX Market Operations will continue to manually input a mass cancellation message into the System consistent with the Participant's instruction to cancel trading interest. Once the mass cancellation message is entered into the System by BX Market Operations, the message will be accepted by the System in the order of receipt in the queue such that the interest that was already accepted into the System will be processed prior to the mass cancellation message. In addition, mass cancellation messages entered into the System by BX Market Operations are handled by the System through the same queuing mechanism that a quote or order message is handled by the System. The Exchange notes its processing of a mass cancellation message inputted by BX Market Operations and handled by the System is consistent with firm quote and order handling rules.

Other Amendments

The Exchange's proposal to correct certain typographical errors and update rulebook citations are not substantive.

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.

Rulebook Harmonization

The Exchange's proposal to reserve various rules in connection with a larger Rulebook harmonization do not impose an undue burden on competition because these amendments are non-substantive.

Definitions

The Exchange's proposal to add the definition of an ''Away Best Bid or Offer'' or ''ABBO'' within Options 1, Section 1(a)(1) and remove the terms ''System Book Feed'' and ''System Securities'' from the Options 1, Section 1 do not impose an undue burden on competition because these amendments will add transparency to the Rulebook.

Relocation of Options 2 Rules

The proposal to relocate Options 2, Section 4(d) and Section 5(e) to Section 6, into Options 6(a) and (b) does not burden competition as this amendment is not substantive.

Removal of Various Listings

Mini Options

The Exchange's proposal to removal references to the listing and handling of Mini Options does not impose an undue burden on competition. Mini Options have not been listed in several years. Also, the Exchange notes that it has no open interest in Mini Options.

U.S. Dollar-Settled Foreign Currency Options

The Exchange's proposal to remove references to the listing of U.S. Dollar-Settled Foreign Currency Options (''FCOs'') does not impose an undue burden on competition. FCOs have not been listed in several years. The Exchange notes that it has no open interest in FCOs.

Mini-Nasdaq-100 Index

The Exchange's proposal to removal references to the listing and handling of Mini-Nasdaq-100 Index options does not impose an undue burden on competition. Mini-Nasdaq-100 Index options have not been listed in several years. Also, the Exchange notes that it has no open interest in Mini-Nasdaq-100 Index options.

Minimum Increments

The Exchange's proposal to relocate parts of Options 3, Section 3 into a new Supplementary Material .01 and add a title for the Penny Pilot Program do not impose an undue burden on competition as these amendments are non-substantive.

Mass Cancellation of Trading Interest

The Exchange's proposal to amend the rule text of the Mass Cancellation of Trading Interest rule within Options 3, Section 19 does not impose an undue burden on competition because there is no corresponding change to the manner in which this service will be offered. It will continue to be offered to all Participants.

Other Amendments

The Exchange's proposal to correct typographical error and update rulebook citations do not impose and undue burden on competition as these amendments are non-substantive.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [11] and subparagraph (f)(6) of Rule 19b–4 thereunder.[12]

A proposed rule change filed under Rule 19b–4(f)(6) [13] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[14] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requests that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange believes that adoption the term ''ABBO,'' would add greater transparency to its rules, and that removing the rule text related to various options listing which are no longer listed on the Exchange will provide Participants with notice of the unavailability of these listing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission waives the 30-day operative delay and designates the proposed rule change operative upon filing.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

[12] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

[15] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2020–001 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2020–001. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2020–001 and should be submitted on or before March 10, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–03101 Filed 2–14–20; 8:45 am]

BILLING CODE 8011–01–P

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88157; File No. SR–DTC–2020–003]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Transition the Application Used for Participant Access to the Imaging Function Relating to Deposited Certificates From a Non-Web-Based Application to a Web-Based Application

February 11, 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 January 31, 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)(4) 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[5] would amend DTC's Procedures[6] set forth in the Deposits Guide and the Custody Guide to provide for an update of DTC's imaging function (''Imaging Function'') relating to Securities certificates deposited by Participants at DTC, through the Deposits service and Custody service, to transition the application used for Participant access to the Imaging Function from a non-web-based application, referred to as the Imaging Fax and Email System (''IFE''), available on DTC's Participant Terminal System (''PTS'') and Participant Browser Service (''PBS''),[7] to a web-based application accessible through PBS, to be named Image Viewer, as discussed below.[8] The proposed rule change to use Image Viewer on PBS as a replacement of IFE would (i) facilitate the modernization of the method of making certificate images available to Participants and (ii) make ministerial and clarifying changes to the text of Procedures set forth in the Deposits Guide and Custody Guide, as discussed below. In addition, DTC would amend the Guide to the DTC Fee Schedule (''Fee Guide'')[9] to conform the description of a fee relating to the Imaging Function to reflect the proposed changes to the Imaging Function, as 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.

[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)(4).

[5] Capitalized terms not otherwise defined in this rule filing are defined as set forth in the Rules, By-Laws and Organization Certificate of DTC (the ''Rules''), *available at http://www.dtcc.com/legal/rules-and-procedures.aspx,* the Deposits Service Guide (''Deposits Guide''), *available at http://www.dtcc.com/~/media/Files/Downloads/legal/service-guides/Deposits.pdf* and the Custody Service Guide (''Custody Guide''), *available at http://www.dtcc.com/~/media/Files/Downloads/legal/service-guides/Custody.pdf.*

[6] Pursuant to the Rules, the term ''Procedures'' means the Procedures, service guides, and regulations of DTC adopted pursuant to Rule 27, as amended from time to time. *See* Rule 1, *supra* note 5. The Procedures include, but are not limited to, the Deposits Guide and the Custody Guide.

[7] PTS is an interface accessible through a designated terminal that allows for Participant input and inquiry into DTC's services. PBS is an interface that allows Participants to make input and inquiry using functionality compatible with internet browser technology.

[8] DTC currently uses an application supported by a vendor for its imaging application. This application is reaching end-of-life because the vendor has notified DTC that it is terminating its support of the application, prompting DTC to replace it with a new application and providing an opportunity to modernize image viewing capabilities. Image Viewer, the application that DTC would implement for the imaging function pursuant to the proposed rule change, has been developed by DTC and would be supported by DTC.

[9] *Available at http://www.dtcc.com/~/media/Files/Downloads/legal/fee-guides/dtcfeeguide.pdf.*

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The proposed rule change would amend DTC's existing Procedures set forth in the Deposits Guide and the Custody Guide to provide for an update of the Imaging Function, to transition the application used for Participant access to the Imaging Function from an application referred to as the IFE, available on PTS and PBS, to a web-based application accessible through PBS, to be named Image Viewer, as discussed below. The proposed rule change to use Image Viewer on PBS as a replacement of IFE would (i) facilitate the modernization of the method of making certificate images available to Participants and (ii) make ministerial and clarifying changes to text of Procedures set forth in the Deposits Guide and Custody Guide, as discussed below. In addition, DTC would amend the Fee Guide to conform the description of a fee relating to the Imaging Function to reflect the proposed changes to the Imaging Function, as described below.

Deposit of Security Certificates With DTC

DTC performs various services for Participants to promote the prompt and accurate clearance and settlement of Securities, including maintaining Accounts that list a Participant's Securities holdings at DTC and allowing Participants to present Securities to be made eligible for DTC's depository and book-entry services. If a Security is accepted by DTC as meeting DTC's eligibility requirements for services and is Deposited with DTC for credit to the Securities Account of a Participant, it becomes an ''Eligible Security.'' [10] Other issues of Securities may be added through corporate actions with respect to Eligible Securities, including events such as name changes, mergers and spinoffs. Prior to processing a corporate action, DTC reviews the subject Securities for continuing eligibility.[11] Thereafter, Participants may Deposit shares of an Eligible Security into their respective DTC Accounts.[12]

Security certificates for Eligible Securities are eligible for Deposit at DTC when they are delivered to DTC in accordance with the Rules and Procedures and pursuant to Article 8 (''Article 8'') of the New York Uniform Commercial Code (''NYUCC'').[13] Under Article 8, a registered owner may transfer a Securities certificate, and the Securities the certificate represents, to a ''purchaser'' (in this case, DTC) by means of indorsement and Delivery.[14] DTC's Rules and Procedures require that the indorsement be made in favor of DTC's nominee, Cede & Co, which is the holder of record of Securities eligible for DTC's book-entry services.[15] Having thereby ''acquired'' the indorsed Security certificate as the purchaser, DTC comes into possession of the rights that the registered owner of the Security would have.[16] Ordinarily, under the DTC Rules and Procedures, the indorsed certificate is presented to the issuer or transfer agent for registration in the name of Cede & Co., so that, in addition to physical possession of the negotiable certificate, Cede & Co. is reflected as the registered holder on the books and records of the issuer maintained by its transfer agent.[17]

Separately, the Custody service enables Participants that hold (i) Securities that (A) are not presently eligible for book-entry services at DTC and/or (B) would otherwise be eligible for DTC book-entry services but are not registered in the name of DTC's nominee, Cede & Co., and/or (ii) certain assets that are not Securities (''Non-Security Assets''), to deposit those Securities and/or Non-Security Assets, as applicable, with DTC for safe-keeping, in accordance with requirements set forth in the Custody Guide.[18] Certificates for Securities and Non-Security Assets deposited through the Custody service are maintained in DTC's secure vault in a Participant's name or a Participant's customer's name (*i.e.,* they are not transferred into DTC's nominee name, Cede & Co).[19] In addition, once a Security is deposited into the Custody service, DTC may perform limited depository services relating to the Security including physical processing for the Security on a Participant's behalf, such as facilitating the transfer of Security Certificates, and providing services available through the Custody Reorganization Service.[20]

Imaging Function

DTC scans certificates that are deposited through the Deposits service or the Custody service to create electronic images that are made available to a Participant via email or facsimile per a request submitted by a Participant through IFE.[21] In order to be able to store or forward images, a Participant must access IFE, where it can request that an image be faxed or emailed to up to six recipients. Once received, an image can be converted into a compatible format, such as .pdf, before it can be stored on the recipient's own system or re-forwarded.

Proposed Replacement of IFE With Image Viewer

As mentioned above, IFE is reaching end-of-life because the vendor that supports it has notified DTC that it is terminating its support of the application, prompting DTC to replace it with a new application that would modernize image viewing capabilities. Image Viewer, the application that DTC would implement for the imaging function pursuant to the proposed rule change, has been developed by DTC and would be supported by DTC.

DTC believes that migrating the Imaging function from IFE, which is not web-based, to the web-based Image Viewer, would provide Participants with a method to obtain electronic images of their certificates that is more compatible with modern systems used by its Participants. Pursuant to the proposed rule change, Image Viewer would allow Participants to view, download and save images of certificates using the new web-based application Image Viewer. Through the new Image Viewer, images would be transmitted in a format that is readily accessible through most modern systems and which may be stored or viewed on the Participant's own systems.

As indicated above, the Image Viewer would only be available via PBS. DTC does not believe this will materially impact Participants' access to the service as all Participants that previously accessed IFE through PTS have connectivity to PBS.

[10] *See* Rule 5, *supra* note 5; DTC Operational Arrangements (Necessary for Securities to Become and Remain Eligible for DTC Services) (''Operational Arrangements''), Section 1, *available at http://www.dtcc.com/~/media/Files/Downloads/legal/issue-eligibility/eligibility/operational-arrangements.pdf.*

[11] *See* Operational Arrangements, Section I, *supra* note 10.

[12] Rule 6, *supra* note 5.

[13] NYUCC 8–101–8–602.

[14] NYUCC 8–301, 8–304, 8–102 and Official Comment 11 thereto.

[15] *See* Rule 6, *supra* note 5.

[16] NYUCC 8–302.

[17] *See* Deposits Guide, *supra* note 5 at 13.

[18] *See* Custody Guide for the types of Securities and Non-Security Assets eligible for deposit to the Custody Service, *supra* note 5, at 5, 12.

[19] *See* Custody Guide, *supra* note 5 at 4.

[20] *See* Custody Guide, *supra* note 5, at 14–17 (providing Procedures for the Custody Reorganization Service). The limited depository services provided by DTC as described above relate only to securities processing functions and do not apply to Non-Security Assets.

[21] *See* Deposits Guide, *supra* note 5 at 21; *See* Custody Guide *supra* note 5 at 4–5.

DTC believes that the capability to distribute facsimile copies of images through IFE has become obsolete as Participants request that images be delivered via email nearly all the time.[22] In this regard, pursuant to the proposed rule change, the option to choose facsimile distribution would be eliminated.

Proposed Rule Change

Pursuant to the proposed rule change DTC would make the following changes to the text of the Deposits Guide:

1. DTC would delete all references to IFE and its functionality, including related methods of distribution of images, throughout the Deposits Guide.

2. DTC would add a new section titled ''Image Viewer'' that describes the functionality for the application as described above, including that a Participant may view, download and save imaged copies of certificates via a web-based Image Viewer, which can be accessed from the following PBS functions:[23]

- Deposit Automation[24]—for regular, bearer[25]/nontransferable,[26] and reorg deposits;[27]
- Branch Inquiry[28]—for branch deposits;
- Restricted Deposit Service[29]—for deposits of certificates bearing a restricted legend;
- Deposit Inquiry—for deposits still in transfer as of the close of business the previous business day;[30] and
- Securities Transfer Legal Deposits—for legal deposits.[31]

3. DTC would revise individual references to imaging functionality included in tables relating to PTS/PBS functions for the Branch Deposits service and RDS to reflect the change that the Imaging Function would be accessible via Image Viewer instead of IFE, as described herein.

Pursuant to the proposed rule change DTC would make the following changes to the text of the Custody Guide:

1. DTC would make the following changes to the Imaging section:

a. Remove the two last paragraphs of the section that describe connectivity specifications necessary to obtain images (through IFE). These specifications would not apply to a Participant's ability to access Image Viewer;

b. Delete references to IFE and any IFE functionality;

c. Add a description that Participants using Image Viewer would have the ability to view, download and save and imaged copies of certificates via Image Viewer; and

d. Consolidate a sentence stating that each item is scanned front and back with another sentence that describes that each deposit ticket, certificate and legal document is scanned.

2. DTC would revise a reference to imaging functionality through IFE in the section titled ''Restricted Deposit Service'' to reflect that Participants would have the ability to view, download and save images of certificates via Image Viewer.

Pursuant to the proposed rule change, DTC would make the following change to the Fee Guide to conform text describing a related fee to the changes to the Imaging Function as described above:

Fee Name	**Amount($)**	**Conditions**
~~**Transmission of image of deposit by fax or e-mail, first recipient**~~ **Request to display/download an Image**	5.50	Per ~~**deposit per**~~ request

Implementation Timeframe

The proposed rule change would be implemented by February 28, 2020, on a date to be announced via a DTC Important Notice. DTC would include a legend on the cover page of the Deposits Guide and the Custody Guide stating (i) that proposed changes to the Procedures, as amended by proposed rule change would be available at *dtcc.com/~/media/Files/Downloads/legal/rule-filings/2020/DTC/SR-DTC-2020-003.pdf,* (ii) that these changes became effective upon filing with the SEC but have not yet been implemented,

[22] During the 12-month period ending November 2019, DTC received a total of approximately 29,000 IFE requests for images, with only 54 (less than .002 percent) of those requests using facsimile as the method of distribution. Although the option to choose facsimile distribution of an image by DTC would not be available upon implementation of the proposed rule change, every Participant has access to PBS and would be able to use Image Viewer upon implementation of the proposed change to retrieve an image. The image would be available to the Participant in a format that could be readily used by the Participant to re-transmit the image via facsimile if the Participant so chooses.

[23] These functions are currently available and are listed in the Deposits Guide for use by Participants for retrieval of certificate images through IFE. Pursuant to the proposed rule change, these functions would instead be used to access Image Viewer functionality.

[24] Deposit Automation is a PBS function that allows a Participant to prepare a deposit through the Deposit Automation System and generate a deposit ticket to be sent to DTC along with the physical Security certificates. *See* Deposits Guide, *supra* note 5 at 7 and 12.

[25] ''Bearer deposit'' refers to the deposit of a bearer Security. A bearer Security is a Security that is not registered with the issuer in the name of the owner and that is negotiable without endorsement and transferred by delivery. *See* Deposits Guide, *supra* note 5 at 10.

[26] Non-transferable Securities are Securities for which transfer services for a Security, typically through the registration of the Security on books maintained by a transfer agent, are not available. *See* Securities Exchange Act Release No. 86897 (September 6, 2019), 84 FR 48187 (September 12, 2019). *See* Deposits Guide, *supra* note 5 at 34–35 for Deposit Procedures relating to non-transferable Securities.

[27] Reorg Deposits refers to the function that allows Participants to deposit an Eligible Security that is undergoing or has undergone a mandatory reorganization, as well as full calls and partial calls. *See* Deposits Guide, *supra* note 5 at 25.

[28] ''Branch inquiry'' allows a Participant to view the status of a Branch Deposit. *See* Deposits Guide, *supra* note 5 at 12. A Branch Deposit refers to a deposit made through the Branch Deposit service where Participant's branch office receives physical certificates from their customers and enter details of the certificates into their internal system. *See* Deposits Guide, *supra* note 5 at 11. The branch office of the Participant then transmits the certificate details to its main office and ships the Securities to DTC. *See id.*

[29] *See* Deposits Guide, *supra* note 5 at 27–30. DTC's Restricted Deposit Service (''RDS'') allows a Participant to deposit restricted securities into a Participant's segregated account within DTC's Custody Service until the applicable restriction has been lifted and the full or partial sale of the securities is complete. *See* Securities Exchange Act Release No. 34–41891 (September 20, 1999), 64 FR 52115 (September 27, 1999). Securities credited to this account will not be registered in the name of Cede & Co. and therefore will not be available for book-entry transfer. *See id.* In addition, RDS functionality allows the processing of a transfer of all or a portion of the securities once the restriction is lifted, and the registration of the unrestricted securities (or portion thereof) in the name of Cede & Co. *See id.*

[30] The ''Deposit Inquiry'' function allows a Participant to receive a report that tracks the Participant's deposit activity. *See* Deposits Guide, *supra* note 5 at 37.

[31] A legal deposit consists of a Security registered in the name of the holder (*i.e.,* not a bearer security) and the legal documentation required for the transfer registration of that Security into the name of DTC's nominee, Cede & Co. *See* Deposits Guide, *supra* note 5 at 16.

(iii) the proposed changes will be implemented by February 28, 2020 on a date to be announced via a DTC Important Notice and (iv) upon implementation, this legend would automatically be removed from these Procedures.

2. Statutory Basis

DTC believes that this proposal is consistent with the requirements of the Act,[32] as described below.

Section 17A(b)(3)(F) of the Act[33] requires, *inter alia,* that the Rules be designed to assure the safeguarding of securities which are in the custody or control of DTC or for which it is responsible. As mentioned above, DTC scans certificates, that are deposited through the Deposits service or the Custody service and then held in DTC's secure vault, to create images that are made available to a Participant in an electronic format. The proposed rule change would migrate the distribution of images of certificates of Securities, to a more flexible application designed to use a web-based platform that would facilitate the accessibility of images to Participants by providing for enhanced compatibility with modern systems used by Participants to obtain the images. In this regard, the proposed rule change would allow DTC to continue to provide images of certificates in an electronic format that is readily accessible to Participants, without the need to remove a certificate from the vault to be able to make and provide a copy to the Participant. Therefore, DTC believes that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act,[34] because it is designed to assure the safeguarding of securities which are in the custody and control of DTC or for which it is responsible, by facilitating an accessible means for Participants to obtain copies of Securities certificates deposited by them without removal of the certificates from DTC's secure vault.

(B) Clearing Agency's Statement on Burden on Competition

DTC does not believe that the proposed rule change will have any impact on competition because neither the decommissioning of IFE nor the elimination of access to the Imaging Function through PTS would affect Participants' ability to access the Imaging Function, as Participants will be able direct their imaging requests through Image Viewer.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to this proposed rule change have not been solicited or received. DTC will notify the Commission of any written comments received by DTC.

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[35] and paragraph (f) of Rule 19b–4 thereunder.[36] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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–2020–003 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–2020–003. 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–2020–003 and should be submitted on or before March 10, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[37]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–03087 Filed 2–14–20; 8:45 am]

BILLING CODE 8011–01–P

[32] 15 U.S.C. 78q–1.

[33] 15 U.S.C. 78q–1(b)(3)(F).

[34] *Id.*

[35] 15 U.S.C. 78s(b)(3)(A).

[36] 17 CFR 240.19b–4(f).

[37] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88160; File No. SR–CboeBYX–2020–006]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the BYX Fee Schedule To Correct an Inadvertent Drafting Error Introduced in a Previous Rule Filing

February 11, 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 January 31, 2020, Cboe BYX Exchange, Inc. (the ''Exchange'' or ''BYX'') 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.

[1] 15 U.S.C.78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BYX Exchange (the ''Exchange'' or ''BYX'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend the BYX Fee Schedule to correct an inadvertent drafting error introduced in a previous rule filing. 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/byx/*), 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 purpose of the proposed rule change is to amend the BYX Fee Schedule to correct an inadvertent drafting error introduced in a previous rule filing that adopted the definition of ''Step-Up Add TCV''.

On January 2, 2020, the Exchange filed a proposed rule change to replace the Non-Displayed Liquidity Incentives with Step-Up Tiers.[3] The purpose of that filing was to offer Step-Up Tiers that would provide Members an opportunity to receive a discounted rate from the standard fee assessment for displayed liquidity adding orders that yield fee codes ''B'',[4] ''V'',[5] or ''Y''.[6] Specifically, to qualify for Tier 1, a Member must have a ''Step-Up Add TCV'' from December 2019 of greater than or equal to 0.05%. Accordingly, the Exchange also adopted a definition of ''Step-Up Add TCV'' to the Fee Schedule which would mean add ADV as a percentage of TCV in the relevant baseline month subtracted from current add ADV as a percentage of TCV. In its adoption of the definition of ''Step-Up Add TCV'', the Exchange inadvertently referenced the terms ''add ADV'' rather than ''ADAV''.[7] Therefore, the Exchange now proposes to amend the definition of Step-Up Add TCV to reference the term ADAV rather than add ADV. The Exchange notes that the proposed definition is substantially consistent with the definition in the Fee Schedules of the Exchange's affiliated exchanges.[8]

2. *Statutory Basis*

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[9] in general, and furthers the objectives of Section 6(b)(4),[10] 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. Specifically, the Exchange believes that the proposed rule change is reasonable, equitable, and not unfairly discriminatory as it does not change the fees or rebates assessed by the Exchange, but rather corrects an inadvertent error to a definition noted in the Fee Schedule. The Exchange believes that amending the terms ''add ADV'' to ''ADAV'' in the definition of ''Step-Up Add TCV'' would reduce confusion around the Exchange's charges and ensure that these fees are appropriately referenced on the Fee Schedule.

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, the proposed rule change is designed to reduce potential confusion to the definition of ''Step-Up Add TCV'' referenced in the Fee Schedule by amending the terms ''add ADV'' to ''ADAV''. The Exchange believes that this change would increase transparency to the benefit of members and investors without having any impact on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from Members or other interested parties.

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)[11] of the Act and subparagraph (f)(2) of Rule 19b–4[12] 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)[13] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–CboeBYX–2020–006 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.

[3] *See* Securities Exchange Act Release No. 34–87960 (January 14, 2020) 85 FR 3437 (January 21, 2020) (SR–CboeBYX–2020–0001[sic]).

[4] ''B'' is appended to displayed orders that add liquidity to BYX(Tape B).

[5] ''V'' is appended to displayed orders that add liquidity to BYX (Tape A).

[6] ''Y'' is appended to displayed order that add liquidity to BYX (Tape C).

[7] ''ADAV'' means average daily volume calculated as the number of shares added per day and ''ADV'' means average daily volume calculated as the number of shares added or removed, combined, per day. ADAV and ADV are calculated on a monthly basis.

[8] See Cboe BZX U.S. Equities Exchange Fee Schedule, Definitions; Cboe EDGX U.S. Equities Exchange Fee Schedule, Definitions.

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(4).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(2).

[13] 15 U.S.C. 78s(b)(2)(B).

All submissions should refer to File No. SR–CboeBYX–2020–006. 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 No. SR–CboeBYX–2020–006, and should be submitted on or before March 10, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–03090 Filed 2–14–20; 8:45 am]

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[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88172; File No. SR–NYSECHX–2020–02]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing of Proposed Rule Change To Establish a Schedule of Wireless Connectivity Fees and Charges With Wireless Connections

February 11, 2020.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on January 30, 2020, the NYSE Chicago, Inc. (''NYSE Chicago'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish a schedule of Wireless Connectivity Fees and Charges (the ''Wireless Fee Schedule'') with wireless connections between the Mahwah, New Jersey data center and other data centers. The proposed change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to establish the Wireless Fee Schedule with wireless connections between the Mahwah, New Jersey data center and three data centers that are owned and operated by third parties unaffiliated with the Exchange: (1) Carteret, New Jersey, (2) Secaucus, New Jersey, and (3) Markham, Canada (collectively, the ''Third Party Data Centers''). Market participants that purchase such a wireless connection (a ''Wireless Connection'') are charged an initial and monthly fee. In addition, the Exchange proposes to include a General Note to the Wireless Fee Schedule.

The Exchange does not believe that the present proposed change is a change to the ''rules of an exchange''[4] required to be filed with the Commission under the Act. The definition of ''exchange'' under the Act includes ''the market facilities maintained by such exchange.''[5] Based on its review of the relevant facts and circumstances, and as discussed further below, the Exchange has concluded that the Wireless Connections are not facilities of the Exchange within the meaning of the Act, and therefore do not need to be included in its rules.

The Exchange is making the current proposal solely because the Staff of the Commission has advised the Exchange that it believes the Wireless Connections are facilities of the Exchange and so must be filed as part of its rules.[6] The Staff has not set forth the basis of its conclusion beyond verbally noting that the Wireless Connections are provided by an affiliate of the Exchange and a market participant could use a Wireless Connection to trade on, or receive the market data of, the Exchange.[7]

The Exchange expects the proposed change to be operative 60 days after the present filing becomes effective.

The Exchange and the ICE Affiliates

To understand the Exchange's conclusion that the Wireless Connections are not facilities of the

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* 15 U.S.C. 78c(a)(27) (defining the term ''rules of an exchange'').

[5] 15 U.S.C. 78c(a)(1). See 15 U.S.C. 78c(a)(2) (defining the term ''facility'' as applied to an exchange).

[6] Telephone conversation between Commission staff and representatives of the Exchange, December 12, 2019.

[7] *Id.* The Commission has previously stated that services were facilities of an exchange subject to the rule filing requirements without fully explaining its reasoning. In 2010, the Commission stated that exchanges had to file proposed rule changes with respect to co-location because ''[t]he Commission views co-location services as being a material aspect of the operation of the facilities of an exchange.'' The Commission did not specify why it reached that conclusion. *See* Securities Exchange Act Release No. 61358 (January 14, 2010), 75 FR 3594 (January 21, 2010) (concept release on equity market structure), at note 76.

In addition, in 2014, the Commission instituted proceedings to determine whether to disapprove a proposed rule change by The NASDAQ Stock Market LLC (''Nasdaq'') on the basis that Nasdaq's ''provision of third-party market data feeds to co-located clients appears to be an integral feature of its co-location program, and co-location programs are subject to the rule filing process.'' Securities Exchange Act Release No. 72654 (July 22, 2014), 79 FR 43808 (July 28, 2014) (SR–NASDAQ–2014–034). In its order, the Commission did not explain why it believed that the provision of third party data was an integral feature of co-location, or if it believed that it was a facility of Nasdaq, although the Nasdaq filing analyzed each prong of the definition of facility in turn. *See* Securities Exchange Act Release No. 71990 (April 22, 2014), 79 FR 23389 (April 28, 2014) (SR–NASDAQ–2014–034).

Exchange within the meaning of the Act, it is important to understand the very real distinction between the Exchange and its corporate affiliates (the ''ICE Affiliates''). The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Around the world, ICE operates seven regulated exchanges in addition to the Exchange and its four national securities exchange affiliates,[8] including futures markets, as well as six clearing houses. Among others, the ICE Affiliates are subject to the jurisdiction of regulators in the U.S., U.K., E.U., the Netherlands, Canada and Singapore.[9] In all, the ICE Affiliates include hundreds of ICE subsidiaries, including more than thirty that are significant legal entity subsidiaries as defined by Commission rule.[10]

Through its ICE Data Services (''IDS'') business,[11] ICE operates the ICE Global Network (''IGN''), a global connectivity network whose infrastructure provides access to over 150 global markets, including the Exchange and Affiliate SROs, and over 750 data sources. All the ICE Affiliates are ultimately controlled by ICE, as the indirect parent company, but generally they do not control each other. In the present case, it is IDS, not the Exchange, that provides the Wireless Connections to market participants. The Exchange does not control IDS.

Wireless Connections

If a market participant wants a connection between one of the Third Party Data Centers and the Mahwah data center, it may opt to purchase a Wireless Connection, for which it will be charged an initial and monthly fee.

Once requested, IDS establishes a Wireless Connection between the IDS equipment in the Third Party Data Center and IDS equipment in the Mahwah data center. IDS contracts with a non-ICE entity to provide the Wireless Connections between the Secaucus and Carteret Third Party Data Centers and the Mahwah data center, through a series of towers equipped with wireless equipment. IDS uses its own wireless network for the Wireless Connection between the Markham Third Party Data Center and the Mahwah data center. At either end of the Wireless Connection, the customer uses a cross connect or other cable to connect its own equipment to the IDS equipment.[12] In the Mahwah data center, the cross connect leads to the customer's server in co-location.

The Wireless Connection does not connect to the Exchange trading and execution systems, nor is it a system of communication from the customer's server in co-location to the trading and execution systems of the Exchange or the Affiliate SROs (collectively, the ''SRO Systems''). Rather, a Wireless Connection facilitates the customer's interaction with itself. Essentially, a Wireless Connection is an empty pipe that a customer can use to communicate between its equipment in co-location and its equipment in the Third Party Data Center.

Customers have control over the data they send over their Wireless Connections. They may, but are not required to, use them to send trading orders to their equipment in co-location; relay Exchange market data, third party market data and public quote feeds from Securities Information Processors; send risk management, billing, or compliance information to their preferred location; or to carry any other market information or other data they wish to and from their equipment in the Third Party Data Centers and Mahwah data center. The Exchange does not, and cannot, know what data customers send over the Wireless Connections. The Exchange does not send or receive any data over the Wireless Connections.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have options. There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Carteret and Secaucus Third Party Data Centers using wireless equipment installed on towers and buildings near the Mahwah data center. Some market participants have their own proprietary wireless networks. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

The Wireless Connections Are Not Facilities of the Exchange

The Definition of ''Exchange''

The definition of ''exchange'' focuses on the exchange entity and what it does:[13]

The term ''exchange'' means any organization, association, or group of persons, whether incorporated or unincorporated, which constitutes, maintains, or provides a market place or facilities for bringing together purchasers and sellers of securities or for otherwise performing with respect to securities the functions commonly performed by a stock exchange as that term is generally understood, and includes the market place and the market facilities maintained by such exchange.

If the ''exchange'' definition included all of an exchange's affiliates, the ''Exchange'' would encompass a global network of futures markets, clearing houses, and data providers, and all of those entities worldwide would be subject to regulation by the Commission. That, however, is not what the definition in the Act provides.

The Exchange and the Affiliate SROs fall squarely within the Act's definition of an ''exchange'': They each provide a market place to bring together purchasers and sellers of securities and perform with respect to securities the functions commonly performed by a stock exchange.

That is not true for the non-exchange ICE Affiliates. Those ICE Affiliates do not provide such a marketplace or perform ''with respect to securities the functions commonly performed by a stock exchange,'' and therefore they are not an ''exchange'' or part of the ''Exchange'' for purposes of the Act. Accordingly, in conducting its analysis, the Exchange does not automatically collapse the ICE Affiliates into the Exchange. The Wireless Connections are also not part of the Exchange, as they are services, and as such cannot be part of an ''organization, association or group of persons'' with the Exchange.

In Rule 3b–16 the Commission further defined the term ''exchange'' under the Act, stating that:[14]

(a) An organization, association, or group of persons shall be considered to constitute, maintain, or provide ''a market place or facilities for bringing together purchasers and sellers of securities or for otherwise performing with respect to securities the functions commonly performed by a stock exchange,'' as those terms are used in

[8] The Exchange's four national securities exchange affiliates are the New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., and NYSE National, Inc. (together, the ''Affiliate SROs'').

[9] Intercontinental Exchange, Inc. Annual Report on Form 10–K for the year ended December 31, 2018, Exhibit 21.1 (filed February 7, 2019), at 15–16.

[10] *Id.* at Exhibit 21.1.

[11] The IDS business operates through several different ICE Affiliates, including NYSE Technologies Connectivity, Inc., an indirect subsidiary of the NYSE.

[12] A cable connects the IDS and customer equipment in the Markham Third Party Data Center. Elsewhere, the customer buys a cross connect from IDS. The cross connects utilized in the Mahwah data center are filed with the Commission. *See* Securities Exchange Act Release No. 87408 (October 28, 2019), 84 FR 58778 (November 1, 2019) (SR–NYSECHX–2019–12), at 58783.

[13] 15 U.S.C. 78c(a)(1).

[14] 17 CFR 240.3b–16(a).

section 3(a)(1) of the Act . . . if such organization, association, or group of persons:

(1) Brings together the orders for securities of multiple buyers and sellers; and

(2) Uses established, non-discretionary methods (whether by providing a trading facility or by setting rules) under which such orders interact with each other, and the buyers and sellers entering such orders agree to the terms of a trade.

The non-exchange ICE Affiliates do not bring ''together orders for securities of multiple buyers and sellers,'' and so are not an ''exchange'' or part of the ''Exchange'' for purposes of Rule 3b–16.

The relevant question, then, is whether the Wireless Connections are ''facilities'' of the Exchange.

The Definition of ''Facility''

The Act defines a ''facility'' [15] as follows:

The term ''facility'' when used with respect to an exchange includes [1] its premises, [2] tangible or intangible property whether on the premises or not, [3] any right to the use of such premises or property or any service thereof for the purpose of effecting or reporting a transaction on an exchange (including, among other things, any system of communication to or from the exchange, by ticker or otherwise, maintained by or with the consent of the exchange), and [4] any right of the exchange to the use of any property or service.

In 2015 the Commission noted that whether something is a ''facility'' is not always black and white, as ''any determination as to whether a service or other product is a facility of an exchange requires an analysis of the particular facts and circumstances.'' [16] Accordingly, the Exchange understands that the specific facts and circumstances of the Wireless Connections must be assessed before a determination can be made regarding whether or not they are facilities of the Exchange.[17]

The first prong of the definition is that ''facility,'' when used with respect to an exchange, includes ''its premises.'' That prong is not applicable in this case, because the Wireless Connections are not premises of the Exchange. The term ''premises'' is generally defined as referring to an entity's building, land, and appurtenances.[18] The wireless network that runs between IDS equipment in the Mahwah data center and IDS equipment in Third Party Data Centers, much of which is actually owned, operated and maintained by a non-ICE entity,[19] does not connect to the Exchange trading and execution systems and is not the premises of the Exchange. The portion of the Mahwah data center where the ''exchange'' functions are performed—*i.e.,* the SRO Systems that bring together purchasers and sellers of securities and perform with respect to securities the functions commonly performed by a stock exchange—could be construed as the ''premises'' of the Exchange, but the same is not true for a wireless network that is almost completely outside of the Mahwah data center.

The second prong of the definition of ''facility'' provides that a facility includes the exchange's ''tangible or intangible property whether on the premises or not.'' The Wireless Connections are not the property of the Exchange: They are services. The underlying wireless network is owned by ICE Affiliates and a non-ICE entity. As noted, the Act does not automatically collapse affiliates into the definition of an ''exchange.'' A review of the facts set forth above shows that there is a real distinction between the Exchange and its ICE Affiliates with respect to the Wireless Connections, and so something owned by an ICE Affiliate is not owned by the Exchange.

The third prong of the definition of ''facility'' provides that a facility includes any right to the use of such premises or property or any service thereof for the purpose of effecting or reporting a transaction on an exchange (including, among other things, any system of communication to or from the exchange, by ticker or otherwise, maintained by or with the consent of the exchange).[20]

This prong does not capture the Wireless Connections because the Exchange does not have the right to use the Wireless Connections to effect or report a transaction on the Exchange. ICE Affiliates and a non-ICE entity own and maintain the wireless network underlying the Wireless Connections, and ICE Affiliates, not the Exchange, offer and provide the Wireless Connections to customers. The Exchange does not know whether or when a market participant has entered into an agreement for a Wireless Connection and has no right to approve or disapprove of the provision of a Wireless Connection, in the same way that the Exchange would have no right to approve or disapprove of the provision of connectivity to a market participant in co-location or elsewhere by any other provider. The Exchange does not put content onto the Wireless Connections. When a customer terminates a Wireless Connection, the Exchange does not consent to the termination.

The Wireless Connections do not connect to the Exchange trading and execution systems. As such, the Wireless Connections are not provided for ''the purpose of effecting or reporting a transaction on'' the Exchange. Rather, a Wireless Connection facilitates the customer's interaction with itself. Each Wireless Connection connects the IDS equipment in the Third Party Data Center and IDS equipment in the Mahwah data center. At either end of the Wireless Connection, the customer uses a cross connect or other cable to connect its own equipment to the IDS equipment. In the Mahwah data center, the cross connect leads to the customer's server in co-location, not the Exchange trading and execution systems.

It is important to remember that the customers' equipment in the Mahwah data center is not provided by, part of, or a facility of, the Exchange. The Exchange provides the space in which customers' equipment is housed, and permits customers to use their equipment to communicate with the SRO Systems through services, such as connections to the local area networks, that are filed with the Commission.[21]

[15] 15 U.S.C. 78c(a)(2).

[16] Securities Exchange Act Release No. 76127 (October 9, 2015), 80 FR 62584 (October 16, 2015) (SR–NYSE–2015–36), at note 9 (order approving proposed rule change amending Section 907.00 of the Listed Company Manual). *See also* 79 FR 23389, *supra* note 7, at note 4 (noting that that the definition of the term ''facility'' has not changed since it was originally adopted) and 23389 (stating that the SEC ''has not separately interpreted the definition of 'facility' '').

[17] As with the definition of ''exchange,'' the ICE Affiliates do not automatically fall within the definition of a ''facility.'' The definition focuses on ownership and the right to use properties and services, not corporate relationships. Indeed, if the term ''exchange'' in the definition of a facility included ''an exchange and its affiliates,'' then the rest of the functional prongs of the facility definition would be meaningless. Fundamental rules of statutory construction dictate that statutes be interpreted to give effect to each of their provisions, so as not to render sections of the statute superfluous.

[18] *See, e.g.,* definition of ''premises'' in Miriam-Webster Dictionary, at *https://www.merriam-webster.com/dictionary/premises,* and Cambridge English Dictionary, at *https://dictionary.cambridge.org/us/dictionary/english/premises.*

[19] A non-ICE entity owns, operates and maintains the wireless network between the Mahwah data center and the Carteret and Secaucus Third Party Data Centers pursuant to an agreement between the non-ICE entity and an ICE Affiliate.

[20] 15 U.S.C. 78c(a)(2).

[21] *See* 83 FR 26314, *supra* note 12. As described by the Commission, co-location is when a ''trading center . . . rents rack space to market participants that enables them to place their servers in close physical proximity to a trading center's matching

Continued

The Exchange provides the space, but not the equipment. Accordingly, even if a customer were to use a Wireless Connection to send instructions to trade or to receive a report of a trade, the customer would not be sending instructions to the Exchange, but rather to its own equipment.

The Exchange believes the example in the parenthetical in the third prong of the definition of ''facility'' cannot be read as an independent prong of the definition. Such a reading would ignore that the parentheses and the word ''including'' clearly indicate that ''any system of communication to or from an exchange . . . maintained by or with the consent of the exchange'' is explaining the preceding text. By its terms, the parenthetical is providing a non-exclusive example of the type of property or service to which the prong refers, and does not remove the requirement that there must be a right to use the premises, property or service to effect or report a transaction on an exchange. It is making sure the reader understands that ''facility'' includes a ticker system that an exchange has the right to use, not creating a new fifth prong to the definition. In fact, if the ''right to use'' requirement were ignored, every communication provider that connected to an exchange, including any broker-dealer system and telecommunications network, would become a facility of that exchange so long as the exchange consented to the connection, whether or not the connection was used to trade or report a trade, and whether or not the exchange had any right at all to the use of the connection.

The fourth prong of the definition provides that a facility includes ''any right of the exchange to the use of any property or service.'' [22] As described above, the Exchange does not have the right to use the Wireless Connections. Instead, the customers of the Wireless Connections are customers who enter into an agreement with ICE Affiliates for connections over a wireless network, much of which is owned, operated and maintained by a non-ICE entity.

Accordingly, for all the reasons discussed above, the Wireless Connections provided by ICE Affiliates are not facilities of the Exchange.

The legal conclusion that the Wireless Connections are not facilities of the Exchange is strongly supported by the facts. The Wireless Connections are neither necessary for, nor integrally connected to, the operations of the Exchange. They are empty pipes that customers can use as they like. In this context, IDS simply acts as a vendor selling connectivity, just like the other vendors that offer wireless connections in the Carteret and Secaucus Third Party Data Centers and fiber connections to all the Third Party Data Centers. The fact that in this case it is ICE Affiliates that offer the Wireless Connections does not make the Wireless Connections facilities of the Exchange any more than are the connections offered by other parties.

Further, the Exchange believes that requiring it to file this proposed rule change is not necessary in order for the Commission to ensure that the Exchange is satisfying its requirements under the Act. Because, as described above, the Wireless Connections are not necessary for, nor connected to, the operations of the Exchange, and customers are not required to use the Wireless Connections, holding the Wireless Connections to the statutory standards in Section 6(b) serves no purpose.

Instead, the sole impact of the requirement that the Exchange file the Wireless Connections is to place an undue burden on competition on the ICE Affiliates that offer the connections, compared to their market competitors. This filing requirement, thus, itself is inconsistent with the requirement under Section 6(b)(8) of the Act that the rules of the exchange not ''impose any burden on competition not necessary or appropriate in furtherance of the purposes of [the Act].'' [23] This burden on competition arises because IDS would be unable, for example, to offer a client or potential client a different bandwidth it requests, without the delay and uncertainty of a filing, but its competitors will. Similarly, if a competitor decides to undercut IDS' fees because IDS, unlike the competitor, has to make its fees public, IDS will not be able to respond quickly, if at all. Indeed, because its competitors are not required to make their services or fees public, and are not subject to a Commission determination of whether such services or fees are ''not unfairly discriminatory'' or equitably allocated, IDS is at a competitive disadvantage from the very start.

The Proposed Service and Fees

As noted above, the Exchange proposes to add to its rules a Wireless Fee Schedule setting forth the fees charged by IDS related to the Wireless Connections between the Mahwah data center and the Third Party Data Centers.

For each Wireless Connection, a customer would be charged a non-recurring initial charge and a monthly recurring charge (''MRC'') that would vary depending upon bandwidth and the location of the connection. The proposal would waive the first month's MRC, to allow customers to test a new Wireless Connection for a month before incurring any MRCs, and the Exchange proposes to add text to the Wireless Fee Schedule accordingly. If a customer had an existing Wireless Connection and opted to upgrade or downgrade to a different size circuit connecting to the same Third Party Access Center, it would not be subject to the initial charge.

The Exchange proposes to establish the Wireless Fee Schedule with a section under the heading ''A. Wireless Connectivity'' setting forth the fees charged by IDS related to the Wireless Connections, as follows:

Type of service	Description	Amount of charge
Wireless Connection between Mahwah Data Center and Secaucus access center.	10 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $9,000.
Wireless Connection between Mahwah Data Center and Secaucus access center.	50 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $13,500.
Wireless Connection between Mahwah Data Center and Secaucus access center.	100 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $23,000.
Wireless Connection between Mahwah Data Center and Secaucus access center.	200 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $44,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	10 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $10,000.

engine.'' 75 FR 3594, *supra* note 7, at 3610 (noting that ''[c]o-location helps minimize network and other types of latencies between the matching engine of trading centers and the servers of market participants'').

[22] *Id.*

[23] 15 U.S.C. 78f(b)(8).

Type of service	Description	Amount of charge
Wireless Connection between Mahwah Data Center and Carteret access center.	50 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $15,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	100 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $25,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	200 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $45,000.
Wireless Connections between (a) Mahwah Data Center and Carteret access center and (b) Mahwah Data Center and Secaucus Data Center.	50 Mb Circuits	$15,000 initial charge for both connections plus monthly charge for both connections of $22,000.
Wireless Connection between Mahwah Data Center and Markham access center.	1 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $6,000.
Wireless Connection between Mahwah Data Center and Markham access center.	5 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $15,500.
Wireless Connection between Mahwah Data Center and Markham access center.	10 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $23,000.

Proposed General Note

The Exchange and each of the Affiliate SROs are filing the Wireless Connections. Although each such market will have a Wireless Fee Schedule, a market participant that obtains a Wireless Connection will not be charged more than once for that service, irrespective of whether it is a member of one, some or none of the Exchange and the Affiliate SROs. Accordingly, the Exchange proposes that the Wireless Fee Schedule include a General Note that describes the billing practice for market participants, as follows:

A market participant that incurs fees from the New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc. or NYSE National, Inc. (collectively, the ''Affiliate SROs'') for a particular service pursuant to this Fee Schedule shall not be subject to fees for the same service charged by the other Affiliate SROs.

The proposed General Note would be consistent with the first general note in the co-location section of the Exchange and Affiliate SROs' price lists and fee schedule,[24] as well as the Nasdaq Stock Market rules.[25]

Application and Impact of the Proposed Change

The proposed change would apply to all market participants equally. The proposed change would not apply differently to distinct types or sizes of market participants. Market participants that require other types or sizes of network connections between the Mahwah data center and the Third Party Data Centers could still request them. The purchase of the service is completely voluntary and the Wireless Fee Schedule will be applied uniformly to all market participants.

Competitive Environment

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have additional options. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

Wireless connections involve beaming signals through the air between antennas that are within sight of one another. Because the signals travel a straight, unimpeded line, and because light waves travel faster through air than through glass (fiber optics), wireless messages have lower latency than messages travelling through fiber optics. At the same time, as a general rule wireless networks have less uptime than fiber networks. Wireless networks are directly and immediately affected by adverse weather conditions, which can cause message loss and outage periods. Wireless networks cannot be configured with redundancy in the same way that fiber networks can. As a result, an equipment or weather issue at any one location on the network will cause the entire network to have an outage. In addition, maintenance can take longer than it would with a fiber based network, as the relevant tower may be in a hard to reach location, or weather conditions may present safety issues, delaying technicians servicing equipment. Even under normal conditions, a wireless network will have a higher error rate than a fiber network of the same length.

The proposed Wireless Connections traverse wireless connections through a series of towers equipped with wireless equipment, including, in the case of the Carteret and Secaucus connections, a pole on the grounds of the Mahwah data center. With the exception of the non-ICE entity that owns the wireless network used for the Wireless Connections to Secaucus and Carteret,[26] third parties do not have access to such pole. However, access to such pole is not required for third parties to establish wireless networks that can compete with the Wireless Connections to the Carteret and Secaucus Third Party Data Centers, as witnessed by the existing wireless connections offered by non-ICE entities currently serving market participants.

Proximity to a data center is not the only determinant of a wireless network's latency. Rather, the latency of a wireless network depends on several factors. Variables include the wireless equipment utilized; the route of, and

[24] *See* Securities Exchange Act Release Nos. 70206 (August 15, 2013), 78 FR 51765 (August 21, 2013) (SR–NYSE–2013–59); 70176 (August 13, 2013), 78 FR 50471 (August 19, 2013) (SR–NYSEMKT–2013–67); 70173 (August 13, 2013), 78 FR 50459 (August 19, 2013) (SR–NYSEArca–2013–80); and 83351 (May 31, 2019), 83 FR 26314 June 6, 2018) (SR–NYSENAT–2018–07), and 84 FR 58778, *supra* note 12, at 58778.

[25] *See, e.g.,* The Nasdaq Stock Market General Equity and Options Rules, General 8, Section 1.

[26] *See* note 19, *supra.*

number of towers or buildings in, the network; and the fiber equipment used at either end of the connection. Moreover, latency is not the only consideration that a market participant may have in selecting a wireless network. Other considerations may include the bandwidth of the offered connection; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

2. Statutory Basis

Although the Exchange does not believe that the present proposed change is a change to the ''rules of an exchange'' [27] required to be filed with the Commission under the Act, the Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[28] in general, and furthers the objectives of Section 6(b)(5) of the Act,[29] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and does not unfairly discriminate between customers, issuers, brokers, or dealers. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[30] 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

The Exchange believes its proposal is reasonable.

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham.

The Wireless Connections provide market participants with one means of connectivity, but substitute products are available, as witnessed by the existing wireless connections offered by non-ICE entities currently serving market participants. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

Market participants' considerations in determining what connectivity to purchase may include latency; bandwidth size; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange believes that the proposed pricing for the Wireless Connections is reasonable because it allows market participants to select the connectivity options that best suit their needs. A market participant that opts to connect with a Wireless Network would be able to select the route and bandwidth that better suit its needs, thereby helping it tailor its operations to the requirements of its business operations. The fees also reflect the benefit received by customers in terms of lower latency over the fiber optics options.

Only market participants that voluntarily select to receive Wireless Connections are charged for them, and those services are available to all market participants. Furthermore, the Exchange believes that the services and fees proposed herein are reasonable because, in addition to the services being completely voluntary, they are available to all market participants on an equal basis (*i.e.,* the same products and services are available to all market participants). All market participants that voluntarily select Wireless Connections would be charged the same amount for the same services and would have their first month's MRC for Wireless Connections waived.

Overall, the Exchange believes that the proposed change is reasonable because the Wireless Connections described herein are offered as a convenience to market participants, but offering them requires the provision, maintenance and operation of the Mahwah data center, wireless networks and access centers in the Third Party Data Centers, including the installation and monitoring, support and maintenance of the services.

The Exchange believes that the proposed waiver of the first month's MRC is reasonable as it would allow customers to test a Wireless Connection for a month before incurring any monthly recurring fees and may act as an incentive to market participants to connect to a Wireless Connection. The Exchange believes that the proposed waiver of the initial charge if a customer has an existing Wireless Connection and opted to upgrade or downgrade to a different size circuit at the same Third Party Data Center is reasonable because the change in Wireless Connection would not require IDS to do any physical work to implement the connection.

The Exchange believes that its proposed General Note is reasonable because it would provide transparency regarding how the billing practice for Wireless Connections functions. The Exchange believes that a customer should not be charged more than once for a Wireless Connection. For example, to charge one customer twice for a Wireless Connection because that customer is a member of two Affiliate SROs, and so subject to the rules of both Affiliate SROs, when another customer that buys the same Wireless Connection only pays once, would not promote just and equitable principles of trade, and could result in the Exchanges and Affiliate SROs receiving the proceeds from multiple fees despite only providing a service once.

The Proposed Change Is an Equitable Allocation of Fees and Credits

The Exchange believes its proposal equitably allocates its fees among its market participants.

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all market participants equally. As is currently the case, the

[27] *See* 15 U.S.C. 78c(a)(27) (defining the term ''rules of an exchange'').

[28] 15 U.S.C. 78f(b).

[29] 15 U.S.C. 78f(b)(5).

[30] 15 U.S.C. 78f(b)(4).

purchase of any connectivity service is completely voluntary and the Wireless Fee Schedule will be applied uniformly to all customers.

Without this proposed rule change, market participants seeking connectivity to a Third Party Data Center would have fewer options. With it, because the Wireless Connections are offered at different bandwidths and price points, market participants have more choices with respect to the form and price of the connectivity they use, allowing a market participant that opts to connect with a wireless network to select the connectivity and bandwidth that better suit its needs, thereby helping it tailor its operations to the requirements of its business operations.

The Exchange believes that its proposed General Note is equitable because a customer would not be charged more than once for a Wireless Connection. For example, to charge one customer twice for a Wireless Connection because that customer is a member of two Affiliate SROs, and so subject to the rules of both Affiliate SROs, when another customer that buys the same Wireless Connection only pays once, would not promote just and equitable principles of trade, and could result in the Exchanges and Affiliate SROs receiving the proceeds from multiple fees despite only providing a service once. The Exchange believes that its proposed General Note is reasonable because it would provide transparency regarding how the billing practice for Wireless Connections functions.

The Proposed Change Is Not Unfairly Discriminatory

The Exchange believes its proposal is not unfairly discriminatory.

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all market participants equally. As is currently the case, the purchase of any connectivity service is completely voluntary and the Wireless Fee Schedule will be applied uniformly to all customers.

Without this proposed rule change, market participants seeking connectivity to a Third Party Data Center would have fewer options. With it, because the Wireless Connections are offered at different bandwidths and price points, market participants have more choices with respect to the form and price of the connectivity they use, allowing a market participant that opts to connect with a wireless network to select the connectivity and bandwidth that better suit its needs, thereby helping it tailor its operations to the requirements of its business operations.

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have additional options. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

Market participants' considerations in determining what connectivity to purchase may include latency; bandwidth size; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange believes that its proposed General Note would not be unfairly discriminatory because a customer would not be charged more than once for a Wireless Connection. For example, to charge one customer twice for a Wireless Connection because that customer is a member of two Affiliate SROs, and so subject to the rules of both Affiliate SROs, when another customer that buys the same Wireless Connection only pays once, would not promote just and equitable principles of trade, and could result in the Exchanges and Affiliate SROs receiving the proceeds from multiple fees despite only providing a service once.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the only burden on competition of the proposed change is on IDS and other commercial connectivity providers. Solely because IDS is wholly owned by the same parent company as the Exchange, IDS will be at a competitive disadvantage to its commercial competitors, and its commercial competitors, without a filing requirement, will be at a relative competitive advantage to IDS.

By permitting IDS to continue to offer the Wireless Connectivity, approval of the proposed changes would contribute to competition by allowing IDS to compete with other connectivity providers, and thus provides market participants another connectivity option. For this reason, the proposed rule changes will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[31]

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham. Importantly, the Exchange does not control the Third Party Data Centers and could not preclude other parties from creating new wireless or fiber connections to any of the Third Party Data Centers.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have additional options. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections

[31] 15 U.S.C. 78f(b)(8).

offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The proposed Wireless Connections traverse wireless connections through a series of towers equipped with wireless equipment, including, in the case of the Carteret and Secaucus connections, a pole on the grounds of the Mahwah data center. With the exception of the non-ICE entity that owns the wireless network used for the Wireless Connections to Secaucus and Carteret,[32] third parties do not have access to such pole, as the IDS wireless network has exclusive rights to operate wireless equipment on the Mahwah data center pole. IDS does not sell rights to third parties to operate wireless equipment on the pole, due to space limitations, security concerns, and the interference that would arise between equipment placed too closely together.

Access to the pole or roof is not required for other parties to establish wireless networks that can compete with the Wireless Connections, as witnessed by the existing wireless connections offered by non-ICE entities currently serving market participants. The latency of a wireless network depends on several factors, not just proximity to a data center. Variables include the wireless equipment utilized; the route of, and number of towers or buildings in, the network; and the fiber equipment used at either end of the connection. In addition, latency is not the only consideration that a market participant may have in selecting a wireless network. Market participants' considerations in determining what connectivity to purchase may include latency; bandwidth size; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions.

The Exchange operates in a highly competitive market in which exchanges and other vendors offer connectivity options between data centers as a means to facilitate the trading and other market activities of market participants. 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 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.'' [33]

The proposed change does not affect competition among national securities exchanges or among members of the Exchange, but rather between IDS and its commercial competitors.

For the reasons described above, the Exchange believes that the proposed rule changes reflect this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or 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 the 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–NYSECHX–2020–02 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSECHX–2020–02. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSECHX–2020–02, and should be submitted on or before March 10, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–03099 Filed 2–14–20; 8:45 am]

BILLING CODE 8011–01–P

[32] *See* note 19, *supra.*

[33] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, at 37499 (June 29, 2005).

[34] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88171; File No. SR–NYSENAT–2020–03]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing of Proposed Rule Change To Establish a Schedule of Wireless Connectivity Fees and Charges With Wireless Connections

February 11, 2020.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on January

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

30, 2020, NYSE National, Inc. (''NYSE National'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish a schedule of Wireless Connectivity Fees and Charges (the ''Wireless Fee Schedule'') with wireless connections between the Mahwah, New Jersey data center and other data centers. 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to establish the Wireless Fee Schedule with wireless connections between the Mahwah, New Jersey data center and three data centers that are owned and operated by third parties unaffiliated with the Exchange: (1) Carteret, New Jersey, (2) Secaucus, New Jersey, and (3) Markham, Canada (collectively, the ''Third Party Data Centers''). Market participants that purchase such a wireless connection (a ''Wireless Connection'') are charged an initial and monthly fee. In addition, the Exchange proposes to include a General Note to the Wireless Fee Schedule.

The Exchange does not believe that the present proposed change is a change to the ''rules of an exchange'' [4] required to be filed with the Commission under the Act. The definition of ''exchange'' under the Act includes ''the market facilities maintained by such exchange.''[5] Based on its review of the relevant facts and circumstances, and as discussed further below, the Exchange has concluded that the Wireless Connections are not facilities of the Exchange within the meaning of the Act, and therefore do not need to be included in its rules.

The Exchange is making the current proposal solely because the Staff of the Commission has advised the Exchange that it believes the Wireless Connections are facilities of the Exchange and so must be filed as part of its rules.[6] The Staff has not set forth the basis of its conclusion beyond verbally noting that the Wireless Connections are provided by an affiliate of the Exchange and a market participant could use a Wireless Connection to trade on, or receive the market data of, the Exchange.[7]

The Exchange expects the proposed change to be operative 60 days after the present filing becomes effective.

The Exchange and the ICE Affiliates

To understand the Exchange's conclusion that the Wireless Connections are not facilities of the Exchange within the meaning of the Act, it is important to understand the very real distinction between the Exchange and its corporate affiliates (the ''ICE Affiliates''). The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Around the world, ICE operates seven regulated exchanges in addition to the Exchange and its four national securities exchange affiliates,[8] including futures markets, as well as six clearing houses. Among others, the ICE Affiliates are subject to the jurisdiction of regulators in the U.S., U.K., E.U., the Netherlands, Canada and Singapore.[9] In all, the ICE Affiliates include hundreds of ICE subsidiaries, including more than thirty that are significant legal entity subsidiaries as defined by Commission rule.[10]

Through its ICE Data Services (''IDS'') business,[11] ICE operates the ICE Global Network (''IGN''), a global connectivity network whose infrastructure provides access to over 150 global markets, including the Exchange and Affiliate SROs, and over 750 data sources. All the ICE Affiliates are ultimately controlled by ICE, as the indirect parent company, but generally they do not control each other. In the present case, it is IDS, not the Exchange, that provides the Wireless Connections to market participants. The Exchange does not control IDS.

Wireless Connections

If a market participant wants a connection between one of the Third Party Data Centers and the Mahwah data center, it may opt to purchase a Wireless Connection, for which it will be charged an initial and monthly fee.

Once requested, IDS establishes a Wireless Connection between the IDS equipment in the Third Party Data Center and IDS equipment in the Mahwah data center. IDS contracts with a non-ICE entity to provide the Wireless Connections between the Secaucus and Carteret Third Party Data Centers and the Mahwah data center, through a series of towers equipped with wireless equipment. IDS uses its own wireless network for the Wireless Connection between the Markham Third Party Data Center and the Mahwah data center. At either end of the Wireless Connection, the customer uses a cross connect or other cable to connect its own

[4] *See* 15 U.S.C. 78c(a)(27) (defining the term ''rules of an exchange'').

[5] 15 U.S.C. 78c(a)(1). See 15 U.S.C. 78c(a)(2) (defining the term ''facility'' as applied to an exchange).

[6] Telephone conversation between Commission staff and representatives of the Exchange, December 12, 2019.

[7] *Id.* The Commission has previously stated that services were facilities of an exchange subject to the rule filing requirements without fully explaining its reasoning. In 2010, the Commission stated that exchanges had to file proposed rule changes with respect to co-location because ''[t]he Commission views co-location services as being a material aspect of the operation of the facilities of an exchange.'' The Commission did not specify why it reached that conclusion. *See* Securities Exchange Act Release No. 61358 (January 14, 2010), 75 FR 3594 (January 21, 2010) (concept release on equity market structure), at note 76.

In addition, in 2014, the Commission instituted proceedings to determine whether to disapprove a proposed rule change by The NASDAQ Stock Market LLC (''Nasdaq'') on the basis that Nasdaq's ''provision of third-party market data feeds to co-located clients appears to be an integral feature of its co-location program, and co-location programs are subject to the rule filing process.'' Securities Exchange Act Release No. 72654 (July 22, 2014), 79 FR 43808 (July 28, 2014) (SR–NASDAQ–2014–034). In its order, the Commission did not explain why it believed that the provision of third party data was an integral feature of co-location, or if it believed that it was a facility of Nasdaq, although the Nasdaq filing analyzed each prong of the definition of facility in turn. *See* Securities Exchange Act Release No. 71990 (April 22, 2014), 79 FR 23389 (April 28, 2014) (SR–NASDAQ–2014–034).

[8] The Exchange's four national securities exchange affiliates are the New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., and NYSE Chicago, Inc. (together, the ''Affiliate SROs'').

[9] Intercontinental Exchange, Inc. Annual Report on Form 10–K for the year ended December 31, 2018, Exhibit 21.1 (filed February 7, 2019), at 15–16.

[10] *Id.* at Exhibit 21.1.

[11] The IDS business operates through several different ICE Affiliates, including NYSE Technologies Connectivity, Inc., an indirect subsidiary of the NYSE.

equipment to the IDS equipment.[12] In the Mahwah data center, the cross connect leads to the customer's server in co-location.

The Wireless Connection does not connect to the Exchange trading and execution systems, nor is it a system of communication from the customer's server in co-location to the trading and execution systems of the Exchange or the Affiliate SROs (collectively, the ''SRO Systems''). Rather, a Wireless Connection facilitates the customer's interaction with itself. Essentially, a Wireless Connection is an empty pipe that a customer can use to communicate between its equipment in co-location and its equipment in the Third Party Data Center.

Customers have control over the data they send over their Wireless Connections. They may, but are not required to, use them to send trading orders to their equipment in co-location; relay Exchange market data, third party market data and public quote feeds from Securities Information Processors; send risk management, billing, or compliance information to their preferred location; or to carry any other market information or other data they wish to and from their equipment in the Third Party Data Centers and Mahwah data center. The Exchange does not, and cannot, know what data customers send over the Wireless Connections. The Exchange does not send or receive any data over the Wireless Connections.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have options. There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Carteret and Secaucus Third Party Data Centers using wireless equipment installed on towers and buildings near the Mahwah data center. Some market participants have their own proprietary wireless networks. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

The Wireless Connections Are Not Facilities of the Exchange

The Definition of ''Exchange''

The definition of ''exchange'' focuses on the exchange entity and what it does:[13]

The term ''exchange'' means any organization, association, or group of persons, whether incorporated or unincorporated, which constitutes, maintains, or provides a market place or facilities for bringing together purchasers and sellers of securities or for otherwise performing with respect to securities the functions commonly performed by a stock exchange as that term is generally understood, and includes the market place and the market facilities maintained by such exchange.

If the ''exchange'' definition included all of an exchange's affiliates, the ''Exchange'' would encompass a global network of futures markets, clearing houses, and data providers, and all of those entities worldwide would be subject to regulation by the Commission. That, however, is not what the definition in the Act provides.

The Exchange and the Affiliate SROs fall squarely within the Act's definition of an ''exchange'': They each provide a market place to bring together purchasers and sellers of securities and perform with respect to securities the functions commonly performed by a stock exchange.

That is not true for the non-exchange ICE Affiliates. Those ICE Affiliates do not provide such a marketplace or perform ''with respect to securities the functions commonly performed by a stock exchange,'' and therefore they are not an ''exchange'' or part of the ''Exchange'' for purposes of the Act. Accordingly, in conducting its analysis, the Exchange does not automatically collapse the ICE Affiliates into the Exchange. The Wireless Connections are also not part of the Exchange, as they are services, and as such cannot be part of an ''organization, association or group of persons'' with the Exchange.

In Rule 3b–16 the Commission further defined the term ''exchange'' under the Act, stating that:[14]

(a) An organization, association, or group of persons shall be considered to constitute, maintain, or provide ''a market place or facilities for bringing together purchasers and sellers of securities or for otherwise performing with respect to securities the functions commonly performed by a stock exchange,'' as those terms are used in section 3(a)(1) of the Act . . . if such organization, association, or group of persons:

(1) Brings together the orders for securities of multiple buyers and sellers; and

(2) Uses established, non-discretionary methods (whether by providing a trading facility or by setting rules) under which such orders interact with each other, and the buyers and sellers entering such orders agree to the terms of a trade.

The non-exchange ICE Affiliates do not bring ''together orders for securities of multiple buyers and sellers,'' and so are not an ''exchange'' or part of the ''Exchange'' for purposes of Rule 3b–16.

The relevant question, then, is whether the Wireless Connections are ''facilities'' of the Exchange.

The Definition of ''Facility''

The Act defines a ''facility''[15] as follows:

The term ''facility'' when used with respect to an exchange includes [1] its premises, [2] tangible or intangible property whether on the premises or not, [3] any right to the use of such premises or property or any service thereof for the purpose of effecting or reporting a transaction on an exchange (including, among other things, any system of communication to or from the exchange, by ticker or otherwise, maintained by or with the consent of the exchange), and [4] any right of the exchange to the use of any property or service.

In 2015 the Commission noted that whether something is a ''facility'' is not always black and white, as ''any determination as to whether a service or other product is a facility of an exchange requires an analysis of the particular facts and circumstances.''[16] Accordingly, the Exchange understands that the specific facts and circumstances of the Wireless Connections must be assessed before a determination can be made regarding whether or not they are facilities of the Exchange.[17]

[12] A cable connects the IDS and customer equipment in the Markham Third Party Data Center. Elsewhere, the customer buys a cross connect from IDS. The cross connects utilized in the Mahwah data center are filed with the Commission. *See* Securities Exchange Act Release No. 83351 (May 31, 2018), 83 FR 26314 (June 6, 2018) (SR–NYSENAT–2018–07, at 26316.

[13] 15 U.S.C. 78c(a)(1).

[14] 17 CFR 240.3b–16(a).

[15] 15 U.S.C. 78c(a)(2).

[16] Securities Exchange Act Release No. 76127 (October 9, 2015), 80 FR 62584 (October 16, 2015) (SR–NYSE–2015–36), at note 9 (order approving proposed rule change amending Section 907.00 of the Listed Company Manual). *See also* 79 FR 23389, *supra* note 7, at note 4 (noting that that the definition of the term ''facility'' has not changed since it was originally adopted) and 23389 (stating that the SEC ''has not separately interpreted the definition of 'facility' '').

[17] As with the definition of ''exchange,'' the ICE Affiliates do not automatically fall within the definition of a ''facility.'' The definition focuses on ownership and the right to use properties and services, not corporate relationships. Indeed, if the term ''exchange'' in the definition of a facility included ''an exchange and its affiliates,'' then the

The first prong of the definition is that ''facility,'' when used with respect to an exchange, includes ''its premises.'' That prong is not applicable in this case, because the Wireless Connections are not premises of the Exchange. The term ''premises'' is generally defined as referring to an entity's building, land, and appurtenances.[18] The wireless network that runs between IDS equipment in the Mahwah data center and IDS equipment in Third Party Data Centers, much of which is actually owned, operated and maintained by a non-ICE entity,[19] does not connect to the Exchange trading and execution systems and is not the premises of the Exchange. The portion of the Mahwah data center where the ''exchange'' functions are performed—*i.e.* the SRO Systems that bring together purchasers and sellers of securities and perform with respect to securities the functions commonly performed by a stock exchange—could be construed as the ''premises'' of the Exchange, but the same is not true for a wireless network that is almost completely outside of the Mahwah data center.

The second prong of the definition of ''facility'' provides that a facility includes the exchange's ''tangible or intangible property whether on the premises or not.'' The Wireless Connections are not the property of the Exchange: They are services. The underlying wireless network is owned by ICE Affiliates and a non-ICE entity. As noted, the Act does not automatically collapse affiliates into the definition of an ''exchange.'' A review of the facts set forth above shows that there is a real distinction between the Exchange and its ICE Affiliates with respect to the Wireless Connections, and so something owned by an ICE Affiliate is not owned by the Exchange.

The third prong of the definition of ''facility'' provides that a facility includes any right to the use of such premises or property or any service thereof for the purpose of effecting or reporting a transaction on an exchange (including, among other things, any system of communication to or from the exchange, by ticker or otherwise, maintained by or with the consent of the exchange).[20]

This prong does not capture the Wireless Connections because the Exchange does not have the right to use the Wireless Connections to effect or report a transaction on the Exchange. ICE Affiliates and a non-ICE entity own and maintain the wireless network underlying the Wireless Connections, and ICE Affiliates, not the Exchange, offer and provide the Wireless Connections to customers. The Exchange does not know whether or when a market participant has entered into an agreement for a Wireless Connection and has no right to approve or disapprove of the provision of a Wireless Connection, in the same way that the Exchange would have no right to approve or disapprove of the provision of connectivity to a market participant in co-location or elsewhere by any other provider. The Exchange does not put content onto the Wireless Connections. When a customer terminates a Wireless Connection, the Exchange does not consent to the termination.

The Wireless Connections do not connect to the Exchange trading and execution systems. As such, the Wireless Connections are not provided for ''the purpose of effecting or reporting a transaction on'' the Exchange. Rather, a Wireless Connection facilitates the customer's interaction with itself. Each Wireless Connection connects the IDS equipment in the Third Party Data Center and IDS equipment in the Mahwah data center. At either end of the Wireless Connection, the customer uses a cross connect or other cable to connect its own equipment to the IDS equipment. In the Mahwah data center, the cross connect leads to the customer's server in co-location, not the Exchange trading and execution systems.

It is important to remember that the customers' equipment in the Mahwah data center is not provided by, part of, or a facility of, the Exchange. The Exchange provides the space in which customers' equipment is housed, and permits customers to use their equipment to communicate with the SRO Systems through services, such as connections to the local area networks, that are filed with the Commission.[21] The Exchange provides the space, but not the equipment. Accordingly, even if a customer were to use a Wireless Connection to send instructions to trade or to receive a report of a trade, the customer would not be sending instructions to the Exchange, but rather to its own equipment.

The Exchange believes the example in the parenthetical in the third prong of the definition of ''facility'' cannot be read as an independent prong of the definition. Such a reading would ignore that the parentheses and the word ''including'' clearly indicate that ''any system of communication to or from an exchange . . . maintained by or with the consent of the exchange'' is explaining the preceding text. By its terms, the parenthetical is providing a non-exclusive example of the type of property or service to which the prong refers, and does not remove the requirement that there must be a right to use the premises, property or service to effect or report a transaction on an exchange. It is making sure the reader understands that ''facility'' includes a ticker system that an exchange has the right to use, not creating a new fifth prong to the definition. In fact, if the ''right to use'' requirement were ignored, every communication provider that connected to an exchange, including any broker-dealer system and telecommunications network, would become a facility of that exchange so long as the exchange consented to the connection, whether or not the connection was used to trade or report a trade, and whether or not the exchange had any right at all to the use of the connection.

The fourth prong of the definition provides that a facility includes ''any right of the exchange to the use of any property or service.''[22] As described above, the Exchange does not have the right to use the Wireless Connections. Instead, the customers of the Wireless Connections are customers who enter into an agreement with ICE Affiliates for connections over a wireless network, much of which is owned, operated and maintained by a non-ICE entity.

Accordingly, for all the reasons discussed above, the Wireless Connections provided by ICE Affiliates are not facilities of the Exchange.

The legal conclusion that the Wireless Connections are not facilities of the Exchange is strongly supported by the facts. The Wireless Connections are

rest of the functional prongs of the facility definition would be meaningless. Fundamental rules of statutory construction dictate that statutes be interpreted to give effect to each of their provisions, so as not to render sections of the statute superfluous.

[18] See, *e.g.,* definition of ''premises'' in Miriam-Webster Dictionary, at *https://www.merriam-webster.com/dictionary/premises,* and Cambridge English Dictionary, at *https://dictionary.cambridge.org/us/dictionary/english/premises.*

[19] A non-ICE entity owns, operates and maintains the wireless network between the Mahwah data center and the Carteret and Secaucus Third Party Data Centers pursuant to an agreement between the non-ICE entity and an ICE Affiliate.

[20] 15 U.S.C. 78c(a)(2).

[21] *See* 83 FR 26314, *supra* note 12. As described by the Commission, co-location is when a ''trading center . . . rents rack space to market participants that enables them to place their servers in close physical proximity to a trading center's matching engine.'' 75 FR 3594, *supra* note 7, at 3610 (noting that ''[c]o-location helps minimize network and other types of latencies between the matching engine of trading centers and the servers of market participants'').

[22] *Id.*

neither necessary for, nor integrally connected to, the operations of the Exchange. They are empty pipes that customers can use as they like. In this context, IDS simply acts as a vendor selling connectivity, just like the other vendors that offer wireless connections in the Carteret and Secaucus Third Party Data Centers and fiber connections to all the Third Party Data Centers. The fact that in this case it is ICE Affiliates that offer the Wireless Connections does not make the Wireless Connections facilities of the Exchange any more than are the connections offered by other parties.

Further, the Exchange believes that requiring it to file this proposed rule change is not necessary in order for the Commission to ensure that the Exchange is satisfying its requirements under the Act. Because, as described above, the Wireless Connections are not necessary for, nor connected to, the operations of the Exchange, and customers are not required to use the Wireless Connections, holding the Wireless Connections to the statutory standards in Section 6(b) serves no purpose.

Instead, the sole impact of the requirement that the Exchange file the Wireless Connections is to place an undue burden on competition on the ICE Affiliates that offer the connections, compared to their market competitors. This filing requirement, thus, itself is inconsistent with the requirement under Section 6(b)(8) of the Act that the rules of the exchange not ''impose any burden on competition not necessary or appropriate in furtherance of the purposes of [the Act].'' [23] This burden on competition arises because IDS would be unable, for example, to offer a client or potential client a different bandwidth it requests, without the delay and uncertainty of a filing, but its competitors will. Similarly, if a competitor decides to undercut IDS' fees because IDS, unlike the competitor, has to make its fees public, IDS will not be able to respond quickly, if at all. Indeed, because its competitors are not required to make their services or fees public, and are not subject to a Commission determination of whether such services or fees are ''not unfairly discriminatory'' or equitably allocated, IDS is at a competitive disadvantage from the very start.

The Proposed Service and Fees

As noted above, the Exchange proposes to add to its rules a Wireless Fee Schedule setting forth the fees charged by IDS related to the Wireless Connections between the Mahwah data center and the Third Party Data Centers.

For each Wireless Connection, a customer would be charged a non-recurring initial charge and a monthly recurring charge (''MRC'') that would vary depending upon bandwidth and the location of the connection. The proposal would waive the first month's MRC, to allow customers to test a new Wireless Connection for a month before incurring any MRCs, and the Exchange proposes to add text to the Wireless Fee Schedule accordingly. If a customer had an existing Wireless Connection and opted to upgrade or downgrade to a different size circuit connecting to the same Third Party Access Center, it would not be subject to the initial charge.

The Exchange proposes to establish the Wireless Fee Schedule with a section under the heading ''A. Wireless Connectivity'' setting forth the fees charged by IDS related to the Wireless Connections, as follows:

Type of service	Description	Amount of charge
Wireless Connection between Mahwah Data Center and Secaucus access center.	10 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $9,000.
Wireless Connection between Mahwah Data Center and Secaucus access center.	50 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $13,500.
Wireless Connection between Mahwah Data Center and Secaucus access center.	100 Mb Circuit. ...	$10,000 per connection initial charge plus monthly charge per connection of $23,000.
Wireless Connection between Mahwah Data Center and Secaucus access center.	200 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $44,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	10 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $10,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	50 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $15,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	100 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $25,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	200 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $45,000.
Wireless Connections between (a) Mahwah Data Center and Carteret access center and (b) Mahwah Data Center and Secaucus Data Center.	50 Mb Circuits	$15,000 initial charge for both connections plus monthly charge for both connections of $22,000.
Wireless Connection between Mahwah Data Center and Markham access center.	1 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $6,000.
Wireless Connection between Mahwah Data Center and Markham access center.	5 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $15,500.
Wireless Connection between Mahwah Data Center and Markham access center.	10 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $23,000.

Proposed General Note

The Exchange and each of the Affiliate SROs are filing the Wireless Connections. Although each such market will have a Wireless Fee Schedule, a market participant that obtains a Wireless Connection will not be charged more than once for that service, irrespective of whether it is a member of one, some or none of the Exchange and the Affiliate SROs. Accordingly, the Exchange proposes that the Wireless Fee Schedule include a General Note that describes the billing practice for market participants, as follows:

A market participant that incurs fees from the New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc. or NYSE National, Inc. (collectively, the

[23] 15 U.S.C. 78f(b)(8).

''Affiliate SROs'') for a particular service pursuant to this Fee Schedule shall not be subject to fees for the same service charged by the other Affiliate SROs.

The proposed General Note would be consistent with the first general note in the co-location section of the Exchange and Affiliate SROs' price lists and fee schedule,[24] as well as the Nasdaq Stock Market rules.[25]

Application and Impact of the Proposed Change

The proposed change would apply to all market participants equally. The proposed change would not apply differently to distinct types or sizes of market participants. Market participants that require other types or sizes of network connections between the Mahwah data center and the Third Party Data Centers could still request them. The purchase of the service is completely voluntary and the Wireless Fee Schedule will be applied uniformly to all market participants.

Competitive Environment

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have additional options. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

Wireless connections involve beaming signals through the air between antennas that are within sight of one another. Because the signals travel a straight, unimpeded line, and because light waves travel faster through air than through glass (fiber optics), wireless messages have lower latency than messages travelling through fiber optics. At the same time, as a general rule wireless networks have less uptime than fiber networks. Wireless networks are directly and immediately affected by adverse weather conditions, which can cause message loss and outage periods. Wireless networks cannot be configured with redundancy in the same way that fiber networks can. As a result, an equipment or weather issue at any one location on the network will cause the entire network to have an outage. In addition, maintenance can take longer than it would with a fiber based network, as the relevant tower may be in a hard to reach location, or weather conditions may present safety issues, delaying technicians servicing equipment. Even under normal conditions, a wireless network will have a higher error rate than a fiber network of the same length.

The proposed Wireless Connections traverse wireless connections through a series of towers equipped with wireless equipment, including, in the case of the Carteret and Secaucus connections, a pole on the grounds of the Mahwah data center. With the exception of the non-ICE entity that owns the wireless network used for the Wireless Connections to Secaucus and Carteret,[26] third parties do not have access to such pole. However, access to such pole is not required for third parties to establish wireless networks that can compete with the Wireless Connections to the Carteret and Secaucus Third Party Data Centers, as witnessed by the existing wireless connections offered by non-ICE entities currently serving market participants.

Proximity to a data center is not the only determinant of a wireless network's latency. Rather, the latency of a wireless network depends on several factors. Variables include the wireless equipment utilized; the route of, and number of towers or buildings in, the network; and the fiber equipment used at either end of the connection. Moreover, latency is not the only consideration that a market participant may have in selecting a wireless network. Other considerations may include the bandwidth of the offered connection; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

2. Statutory Basis

Although the Exchange does not believe that the present proposed change is a change to the ''rules of an exchange'' [27] required to be filed with the Commission under the Act, the Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[28] in general, and furthers the objectives of Section 6(b)(5) of the Act,[29] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and does not unfairly discriminate between customers, issuers, brokers, or dealers. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[30] 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

The Exchange believes its proposal is reasonable.

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes

[24] *See* Securities Exchange Act Release Nos. 70206 (August 15, 2013), 78 FR 51765 (August 21, 2013) (SR–NYSE–2013–59); 70176 (August 13, 2013), 78 FR 50471 (August 19, 2013) (SR–NYSEMKT–2013–67); 70173 (August 13, 2013), 78 FR 50459 (August 19, 2013) (SR–NYSEArca–2013–80); and 87408 (October 28, 2019), 84 FR 58778 (November 1, 2019) (SR–NYSECHX–2019–12), and 83 FR 26314, *supra* note 12, at 26314.

[25] *See, e.g.,* The Nasdaq Stock Market General Equity and Options Rules, General 8, Section 1.

[26] *See* note 19, *supra.*

[27] *See* 15 U.S.C. 78c(a)(27) (defining the term ''rules of an exchange'').

[28] 15 U.S.C. 78f(b).

[29] 15 U.S.C. 78f(b)(5).

[30] 15 U.S.C. 78f(b)(4).

that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham.

The Wireless Connections provide market participants with one means of connectivity, but substitute products are available, as witnessed by the existing wireless connections offered by non-ICE entities currently serving market participants. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

Market participants' considerations in determining what connectivity to purchase may include latency; bandwidth size; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange believes that the proposed pricing for the Wireless Connections is reasonable because it allows market participants to select the connectivity options that best suit their needs. A market participant that opts to connect with a Wireless Network would be able to select the route and bandwidth that better suit its needs, thereby helping it tailor its operations to the requirements of its business operations. The fees also reflect the benefit received by customers in terms of lower latency over the fiber optics options.

Only market participants that voluntarily select to receive Wireless Connections are charged for them, and those services are available to all market participants. Furthermore, the Exchange believes that the services and fees proposed herein are reasonable because, in addition to the services being completely voluntary, they are available to all market participants on an equal basis (*i.e.,* the same products and services are available to all market participants). All market participants that voluntarily select Wireless Connections would be charged the same amount for the same services and would have their first month's MRC for Wireless Connections waived.

Overall, the Exchange believes that the proposed change is reasonable because the Wireless Connections described herein are offered as a convenience to market participants, but offering them requires the provision, maintenance and operation of the Mahwah data center, wireless networks and access centers in the Third Party Data Centers, including the installation and monitoring, support and maintenance of the services.

The Exchange believes that the proposed waiver of the first month's MRC is reasonable as it would allow customers to test a Wireless Connection for a month before incurring any monthly recurring fees and may act as an incentive to market participants to connect to a Wireless Connection. The Exchange believes that the proposed waiver of the initial charge if a customer has an existing Wireless Connection and opted to upgrade or downgrade to a different size circuit at the same Third Party Data Center is reasonable because the change in Wireless Connection would not require IDS to do any physical work to implement the connection.

The Exchange believes that its proposed General Note is reasonable because it would provide transparency regarding how the billing practice for Wireless Connections functions. The Exchange believes that a customer should not be charged more than once for a Wireless Connection. For example, to charge one customer twice for a Wireless Connection because that customer is a member of two Affiliate SROs, and so subject to the rules of both Affiliate SROs, when another customer that buys the same Wireless Connection only pays once, would not promote just and equitable principles of trade, and could result in the Exchanges and Affiliate SROs receiving the proceeds from multiple fees despite only providing a service once.

The Proposed Change is an Equitable Allocation of Fees and Credits

The Exchange believes its proposal equitably allocates its fees among its market participants.

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all market participants equally. As is currently the case, the purchase of any connectivity service is completely voluntary and the Wireless Fee Schedule will be applied uniformly to all customers.

Without this proposed rule change, market participants seeking connectivity to a Third Party Data Center would have fewer options. With it, because the Wireless Connections are offered at different bandwidths and price points, market participants have more choices with respect to the form and price of the connectivity they use, allowing a market participant that opts to connect with a wireless network to select the connectivity and bandwidth that better suit its needs, thereby helping it tailor its operations to the requirements of its business operations.

The Exchange believes that its proposed General Note is equitable because a customer would not be charged more than once for a Wireless Connection. For example, to charge one customer twice for a Wireless Connection because that customer is a member of two Affiliate SROs, and so subject to the rules of both Affiliate SROs, when another customer that buys the same Wireless Connection only pays once, would not promote just and equitable principles of trade, and could result in the Exchanges and Affiliate SROs receiving the proceeds from multiple fees despite only providing a service once. The Exchange believes that its proposed General Note is reasonable because it would provide transparency regarding how the billing practice for Wireless Connections functions.

The Proposed Change is Not Unfairly Discriminatory

The Exchange believes its proposal is not unfairly discriminatory.

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all market participants equally. As is currently the case, the purchase of any connectivity service is completely voluntary and the Wireless Fee Schedule will be applied uniformly to all customers.

Without this proposed rule change, market participants seeking connectivity to a Third Party Data Center would have fewer options. With it, because the Wireless Connections are offered at different bandwidths and price points, market participants have more choices with respect to the form and price of the connectivity they use, allowing a market participant that opts to connect with a wireless network to select the connectivity and bandwidth that better suit its needs, thereby helping it tailor its operations to the requirements of its business operations.

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party

Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have additional options. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

Market participants' considerations in determining what connectivity to purchase may include latency; bandwidth size; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange believes that its proposed General Note would not be unfairly discriminatory because a customer would not be charged more than once for a Wireless Connection. For example, to charge one customer twice for a Wireless Connection because that customer is a member of two Affiliate SROs, and so subject to the rules of both Affiliate SROs, when another customer that buys the same Wireless Connection only pays once, would not promote just and equitable principles of trade, and could result in the Exchanges and Affiliate SROs receiving the proceeds from multiple fees despite only providing a service once.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the only burden on competition of the proposed change is on IDS and other commercial connectivity providers. Solely because IDS is wholly owned by the same parent company as the Exchange, IDS will be at a competitive disadvantage to its commercial competitors, and its commercial competitors, without a filing requirement, will be at a relative competitive advantage to IDS.

By permitting IDS to continue to offer the Wireless Connectivity, approval of the proposed changes would contribute to competition by allowing IDS to compete with other connectivity providers, and thus provides market participants another connectivity option. For this reason, the proposed rule changes will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[31]

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham. Importantly, the Exchange does not control the Third Party Data Centers and could not preclude other parties from creating new wireless or fiber connections to any of the Third Party Data Centers.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have additional options. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The proposed Wireless Connections traverse wireless connections through a series of towers equipped with wireless equipment, including, in the case of the Carteret and Secaucus connections, a pole on the grounds of the Mahwah data center. With the exception of the non-ICE entity that owns the wireless network used for the Wireless Connections to Secaucus and Carteret,[32] third parties do not have access to such pole, as the IDS wireless network has exclusive rights to operate wireless equipment on the Mahwah data center pole. IDS does not sell rights to third parties to operate wireless equipment on the pole, due to space limitations, security concerns, and the interference that would arise between equipment placed too closely together.

Access to the pole or roof is not required for other parties to establish wireless networks that can compete with the Wireless Connections, as witnessed by the existing wireless connections offered by non-ICE entities currently serving market participants. The latency of a wireless network depends on several factors, not just proximity to a data center. Variables include the wireless equipment utilized; the route of, and number of towers or buildings in, the network; and the fiber equipment used at either end of the connection. In addition, latency is not the only consideration that a market participant may have in selecting a wireless network. Market participants' considerations in determining what connectivity to purchase may include latency; bandwidth size; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions.

The Exchange operates in a highly competitive market in which exchanges and other vendors offer connectivity options between data centers as a means to facilitate the trading and other market activities of market participants. 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 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.'' [33]

[31] 15 U.S.C. 78f(b)(8).

[32] *See* note 19, *supra.*

[33] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, at 37499 (June 29, 2005).

The proposed change does not affect competition among national securities exchanges or among members of the Exchange, but rather between IDS and its commercial competitors.

For the reasons described above, the Exchange believes that the proposed rule changes reflect this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or 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 the 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–NYSENAT–2020–03 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSENAT–2020–03. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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–NYSENAT–2020–03, and should be submitted on or before March 10, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–03098 Filed 2–14–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88168; File No. SR–NYSE–2020–05]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change To Establish a Schedule of Wireless Connectivity Fees and Charges With Wireless Connections

February 11, 2020.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on January 30, 2020, New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish a schedule of Wireless Connectivity Fees and Charges (the ''Wireless Fee Schedule'') with wireless connections between the Mahwah, New Jersey data center and other data centers. 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to establish the Wireless Fee Schedule with wireless connections between the Mahwah, New Jersey data center and three data centers that are owned and operated by third parties unaffiliated with the Exchange: (1) Carteret, New Jersey, (2) Secaucus, New Jersey, and (3) Markham, Canada (collectively, the ''Third Party Data Centers''). Market participants that purchase such a wireless connection (a ''Wireless Connection'') are charged an initial and monthly fee. In addition, the Exchange proposes to include a General Note to the Wireless Fee Schedule.

The Exchange does not believe that the present proposed change is a change to the ''rules of an exchange''[4] required to be filed with the Commission under the Act. The definition of ''exchange'' under the Act includes ''the market facilities maintained by such

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[34] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* 15 U.S.C. 78c(a)(27) (defining the term ''rules of an exchange'').

exchange.'' [5] Based on its review of the relevant facts and circumstances, and as discussed further below, the Exchange has concluded that the Wireless Connections are not facilities of the Exchange within the meaning of the Act, and therefore do not need to be included in its rules.

The Exchange is making the current proposal solely because the Staff of the Commission has advised the Exchange that it believes the Wireless Connections are facilities of the Exchange and so must be filed as part of its rules.[6] The Staff has not set forth the basis of its conclusion beyond verbally noting that the Wireless Connections are provided by an affiliate of the Exchange and a market participant could use a Wireless Connection to trade on, or receive the market data of, the Exchange.[7]

The Exchange expects the proposed change to be operative 60 days after the present filing becomes effective.

The Exchange and the ICE Affiliates

To understand the Exchange's conclusion that the Wireless Connections are not facilities of the Exchange within the meaning of the Act, it is important to understand the very real distinction between the Exchange and its corporate affiliates (the ''ICE Affiliates''). The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Around the world, ICE operates seven regulated exchanges in addition to the Exchange and its four national securities exchange affiliates,[8] including futures markets, as well as six clearing houses. Among others, the ICE Affiliates are subject to the jurisdiction of regulators in the U.S., U.K., E.U., the Netherlands, Canada and Singapore.[9] In all, the ICE Affiliates include hundreds of ICE subsidiaries, including more than thirty that are significant legal entity subsidiaries as defined by Commission rule.[10]

Through its ICE Data Services (''IDS'') business,[11] ICE operates the ICE Global Network (''IGN''), a global connectivity network whose infrastructure provides access to over 150 global markets, including the Exchange and Affiliate SROs, and over 750 data sources. All the ICE Affiliates are ultimately controlled by ICE, as the indirect parent company, but generally they do not control each other. In the present case, it is IDS, not the Exchange, that provides the Wireless Connections to market participants. The Exchange does not control IDS.

Wireless Connections

If a market participant wants a connection between one of the Third Party Data Centers and the Mahwah data center, it may opt to purchase a Wireless Connection, for which it will be charged an initial and monthly fee.

Once requested, IDS establishes a Wireless Connection between the IDS equipment in the Third Party Data Center and IDS equipment in the Mahwah data center. IDS contracts with a non-ICE entity to provide the Wireless Connections between the Secaucus and Carteret Third Party Data Centers and the Mahwah data center, through a series of towers equipped with wireless equipment. IDS uses its own wireless network for the Wireless Connection between the Markham Third Party Data Center and the Mahwah data center. At either end of the Wireless Connection, the customer uses a cross connect or other cable to connect its own equipment to the IDS equipment.[12] In the Mahwah data center, the cross connect leads to the customer's server in co-location.

The Wireless Connection does not connect to the Exchange trading and execution systems, nor is it a system of communication from the customer's server in co-location to the trading and execution systems of the Exchange or the Affiliate SROs (collectively, the ''SRO Systems''). Rather, a Wireless Connection facilitates the customer's interaction with itself. Essentially, a Wireless Connection is an empty pipe that a customer can use to communicate between its equipment in co-location and its equipment in the Third Party Data Center.

Customers have control over the data they send over their Wireless Connections. They may, but are not required to, use them to send trading orders to their equipment in co-location; relay Exchange market data, third party market data and public quote feeds from Securities Information Processors; send risk management, billing, or compliance information to their preferred location; or to carry any other market information or other data they wish to and from their equipment in the Third Party Data Centers and Mahwah data center. The Exchange does not, and cannot, know what data customers send over the Wireless Connections. The Exchange does not send or receive any data over the Wireless Connections.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have options. There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Carteret and Secaucus Third Party Data Centers using wireless equipment installed on towers and buildings near the Mahwah data center. Some market participants have their own proprietary wireless networks. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

The Wireless Connections Are Not Facilities of the Exchange

The Definition of ''Exchange''

The definition of ''exchange'' focuses on the exchange entity and what it does: [13]

The term ''exchange'' means any organization, association, or group of

[5] 15 U.S.C. 78c(a)(1). See 15 U.S.C. 78c(a)(2) (defining the term ''facility'' as applied to an exchange).

[6] Telephone conversation between Commission staff and representatives of the Exchange, December 12, 2019.

[7] *Id.* The Commission has previously stated that services were facilities of an exchange subject to the rule filing requirements without fully explaining its reasoning. In 2010, the Commission stated that exchanges had to file proposed rule changes with respect to co-location because ''[t]he Commission views co-location services as being a material aspect of the operation of the facilities of an exchange.'' The Commission did not specify why it reached that conclusion. *See* Securities Exchange Act Release No. 61358 (January 14, 2010), 75 FR 3594 (January 21, 2010) (concept release on equity market structure), at note 76.

In addition, in 2014, the Commission instituted proceedings to determine whether to disapprove a proposed rule change by The NASDAQ Stock Market LLC (''Nasdaq'') on the basis that Nasdaq's ''provision of third-party market data feeds to co-located clients appears to be an integral feature of its co-location program, and co-location programs are subject to the rule filing process.'' Securities Exchange Act Release No. 72654 (July 22, 2014), 79 FR 43808 (July 28, 2014) (SR–NASDAQ–2014–034). In its order, the Commission did not explain why it believed that the provision of third party data was an integral feature of co-location, or if it believed that it was a facility of Nasdaq, although the Nasdaq filing analyzed each prong of the definition of facility in turn. *See* Securities Exchange Act Release No. 71990 (April 22, 2014), 79 FR 23389 (April 28, 2014) (SR–NASDAQ–2014–034).

[8] The Exchange's four national securities exchange affiliates are NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc. (together, the ''Affiliate SROs'').

[9] Intercontinental Exchange, Inc. Annual Report on Form 10–K for the year ended December 31, 2018, Exhibit 21.1 (filed February 7, 2019), at 15–16.

[10] *Id.* at Exhibit 21.1.

[11] The IDS business operates through several different ICE Affiliates, including NYSE Technologies Connectivity, Inc., an indirect subsidiary of the NYSE.

[12] A cable connects the IDS and customer equipment in the Markham Third Party Data Center. Elsewhere, the customer buys a cross connect from IDS. The cross connects utilized in the Mahwah data center are filed with the Commission. *See* Securities Exchange Act Release No. 67666 (August 15, 2012), 77 FR 50742 (August 22, 2012) (SR–NYSE–2012–18).

[13] 15 U.S.C. 78c(a)(1).

persons, whether incorporated or unincorporated, which constitutes, maintains, or provides a market place or facilities for bringing together purchasers and sellers of securities or for otherwise performing with respect to securities the functions commonly performed by a stock exchange as that term is generally understood, and includes the market place and the market facilities maintained by such exchange.

If the ''exchange'' definition included all of an exchange's affiliates, the ''Exchange'' would encompass a global network of futures markets, clearing houses, and data providers, and all of those entities worldwide would be subject to regulation by the Commission. That, however, is not what the definition in the Act provides.

The Exchange and the Affiliate SROs fall squarely within the Act's definition of an ''exchange'': They each provide a market place to bring together purchasers and sellers of securities and perform with respect to securities the functions commonly performed by a stock exchange.

That is not true for the non-exchange ICE Affiliates. Those ICE Affiliates do not provide such a marketplace or perform ''with respect to securities the functions commonly performed by a stock exchange,'' and therefore they are not an ''exchange'' or part of the ''Exchange'' for purposes of the Act. Accordingly, in conducting its analysis, the Exchange does not automatically collapse the ICE Affiliates into the Exchange. The Wireless Connections are also not part of the Exchange, as they are services, and as such cannot be part of an ''organization, association or group of persons'' with the Exchange.

In Rule 3b–16 the Commission further defined the term ''exchange'' under the Act, stating that: [14]

(a) An organization, association, or group of persons shall be considered to constitute, maintain, or provide ''a market place or facilities for bringing together purchasers and sellers of securities or for otherwise performing with respect to securities the functions commonly performed by a stock exchange,'' as those terms are used in section 3(a)(1) of the Act . . . if such organization, association, or group of persons:

(1) Brings together the orders for securities of multiple buyers and sellers; and

(2) Uses established, non-discretionary methods (whether by providing a trading facility or by setting rules) under which such orders interact with each other, and the buyers and sellers entering such orders agree to the terms of a trade.

The non-exchange ICE Affiliates do not bring ''together orders for securities of multiple buyers and sellers,'' and so are not an ''exchange'' or part of the ''Exchange'' for purposes of Rule 3b–16.

The relevant question, then, is whether the Wireless Connections are ''facilities'' of the Exchange.

The Definition of ''Facility''

The Act defines a ''facility'' [15] as follows:

The term ''facility'' when used with respect to an exchange includes [1] its premises, [2] tangible or intangible property whether on the premises or not, [3] any right to the use of such premises or property or any service thereof for the purpose of effecting or reporting a transaction on an exchange (including, among other things, any system of communication to or from the exchange, by ticker or otherwise, maintained by or with the consent of the exchange), and [4] any right of the exchange to the use of any property or service.

In 2015 the Commission noted that whether something is a ''facility'' is not always black and white, as ''any determination as to whether a service or other product is a facility of an exchange requires an analysis of the particular facts and circumstances.'' [16] Accordingly, the Exchange understands that the specific facts and circumstances of the Wireless Connections must be assessed before a determination can be made regarding whether or not they are facilities of the Exchange.[17]

The first prong of the definition is that ''facility,'' when used with respect to an exchange, includes ''its premises.'' That prong is not applicable in this case, because the Wireless Connections are not premises of the Exchange. The term ''premises'' is generally defined as referring to an entity's building, land, and appurtenances.[18] The wireless network that runs between IDS equipment in the Mahwah data center and IDS equipment in Third Party Data Centers, much of which is actually owned, operated and maintained by a non-ICE entity,[19] does not connect to the Exchange trading and execution systems and is not the premises of the Exchange. The portion of the Mahwah data center where the ''exchange'' functions are performed—*i.e.* the SRO Systems that bring together purchasers and sellers of securities and perform with respect to securities the functions commonly performed by a stock exchange—could be construed as the ''premises'' of the Exchange, but the same is not true for a wireless network that is almost completely outside of the Mahwah data center.

The second prong of the definition of ''facility'' provides that a facility includes the exchange's ''tangible or intangible property whether on the premises or not.'' The Wireless Connections are not the property of the Exchange: They are services. The underlying wireless network is owned by ICE Affiliates and a non-ICE entity. As noted, the Act does not automatically collapse affiliates into the definition of an ''exchange.'' A review of the facts set forth above shows that there is a real distinction between the Exchange and its ICE Affiliates with respect to the Wireless Connections, and so something owned by an ICE Affiliate is not owned by the Exchange.

The third prong of the definition of ''facility'' provides that a facility includes any right to the use of such premises or property or any service thereof for the purpose of effecting or reporting a transaction on an exchange (including, among other things, any system of communication to or from the exchange, by ticker or otherwise, maintained by or with the consent of the exchange).[20]

This prong does not capture the Wireless Connections because the Exchange does not have the right to use the Wireless Connections to effect or report a transaction on the Exchange.

[14] 17 CFR 240.3b–16(a).

[15] 15 U.S.C. 78c(a)(2).

[16] Securities Exchange Act Release No. 76127 (October 9, 2015), 80 FR 62584 (October 16, 2015) (SR–NYSE–2015–36), at note 9 (order approving proposed rule change amending Section 907.00 of the Listed Company Manual). *See also* 79 FR 23389, *supra* note 7, at note 4 (noting that that the definition of the term ''facility'' has not changed since it was originally adopted) and 23389 (stating that the SEC ''has not separately interpreted the definition of 'facility' '').

[17] As with the definition of ''exchange,'' the ICE Affiliates do not automatically fall within the definition of a ''facility.'' The definition focuses on ownership and the right to use properties and services, not corporate relationships. Indeed, if the term ''exchange'' in the definition of a facility included ''an exchange and its affiliates,'' then the rest of the functional prongs of the facility definition would be meaningless. Fundamental rules of statutory construction dictate that statutes be interpreted to give effect to each of their provisions, so as not to render sections of the statute superfluous.

[18] *See, e.g.,* definition of ''premises'' in Miriam-Webster Dictionary, at *https://www.merriam-webster.com/dictionary/premises,* and Cambridge English Dictionary, at *https://dictionary.cambridge.org/us/dictionary/english/premises.*

[19] A non-ICE entity owns, operates and maintains the wireless network between the Mahwah data center and the Carteret and Secaucus Third Party Data Centers pursuant to an agreement between the non-ICE entity and an ICE Affiliate.

[20] 15 U.S.C. 78c(a)(2).

ICE Affiliates and a non-ICE entity own and maintain the wireless network underlying the Wireless Connections, and ICE Affiliates, not the Exchange, offer and provide the Wireless Connections to customers. The Exchange does not know whether or when a market participant has entered into an agreement for a Wireless Connection and has no right to approve or disapprove of the provision of a Wireless Connection, in the same way that the Exchange would have no right to approve or disapprove of the provision of connectivity to a market participant in co-location or elsewhere by any other provider. The Exchange does not put content onto the Wireless Connections. When a customer terminates a Wireless Connection, the Exchange does not consent to the termination.

The Wireless Connections do not connect to the Exchange trading and execution systems. As such, the Wireless Connections are not provided for ''the purpose of effecting or reporting a transaction on'' the Exchange. Rather, a Wireless Connection facilitates the customer's interaction with itself. Each Wireless Connection connects the IDS equipment in the Third Party Data Center and IDS equipment in the Mahwah data center. At either end of the Wireless Connection, the customer uses a cross connect or other cable to connect its own equipment to the IDS equipment. In the Mahwah data center, the cross connect leads to the customer's server in co-location, not the Exchange trading and execution systems.

It is important to remember that the customers' equipment in the Mahwah data center is not provided by, part of, or a facility of, the Exchange. The Exchange provides the space in which customers' equipment is housed, and permits customers to use their equipment to communicate with the SRO Systems through services, such as connections to the local area networks, that are filed with the Commission.[21] The Exchange provides the space, but not the equipment. Accordingly, even if a customer were to use a Wireless Connection to send instructions to trade or to receive a report of a trade, the customer would not be sending instructions to the Exchange, but rather to its own equipment.

The Exchange believes the example in the parenthetical in the third prong of the definition of ''facility'' cannot be read as an independent prong of the definition. Such a reading would ignore that the parentheses and the word ''including'' clearly indicate that ''any system of communication to or from an exchange . . . maintained by or with the consent of the exchange'' is explaining the preceding text. By its terms, the parenthetical is providing a non-exclusive example of the type of property or service to which the prong refers, and does not remove the requirement that there must be a right to use the premises, property or service to effect or report a transaction on an exchange. It is making sure the reader understands that ''facility'' includes a ticker system that an exchange has the right to use, not creating a new fifth prong to the definition. In fact, if the ''right to use'' requirement were ignored, every communication provider that connected to an exchange, including any broker-dealer system and telecommunications network, would become a facility of that exchange so long as the exchange consented to the connection, whether or not the connection was used to trade or report a trade, and whether or not the exchange had any right at all to the use of the connection.

The fourth prong of the definition provides that a facility includes ''any right of the exchange to the use of any property or service.''[22] As described above, the Exchange does not have the right to use the Wireless Connections. Instead, the customers of the Wireless Connections are customers who enter into an agreement with ICE Affiliates for connections over a wireless network, much of which is owned, operated and maintained by a non-ICE entity.

Accordingly, for all the reasons discussed above, the Wireless Connections provided by ICE Affiliates are not facilities of the Exchange.

The legal conclusion that the Wireless Connections are not facilities of the Exchange is strongly supported by the facts. The Wireless Connections are neither necessary for, nor integrally connected to, the operations of the Exchange. They are empty pipes that customers can use as they like. In this context, IDS simply acts as a vendor selling connectivity, just like the other vendors that offer wireless connections in the Carteret and Secaucus Third Party Data Centers and fiber connections to all the Third Party Data Centers. The fact that in this case it is ICE Affiliates that offer the Wireless Connections does not make the Wireless Connections facilities of the Exchange any more than are the connections offered by other parties.

Further, the Exchange believes that requiring it to file this proposed rule change is not necessary in order for the Commission to ensure that the Exchange is satisfying its requirements under the Act. Because, as described above, the Wireless Connections are not necessary for, nor connected to, the operations of the Exchange, and customers are not required to use the Wireless Connections, holding the Wireless Connections to the statutory standards in Section 6(b) serves no purpose.

Instead, the sole impact of the requirement that the Exchange file the Wireless Connections is to place an undue burden on competition on the ICE Affiliates that offer the connections, compared to their market competitors. This filing requirement, thus, itself is inconsistent with the requirement under Section 6(b)(8) of the Act that the rules of the exchange not ''impose any burden on competition not necessary or appropriate in furtherance of the purposes of [the Act].''[23] This burden on competition arises because IDS would be unable, for example, to offer a client or potential client a different bandwidth it requests, without the delay and uncertainty of a filing, but its competitors will. Similarly, if a competitor decides to undercut IDS' fees because IDS, unlike the competitor, has to make its fees public, IDS will not be able to respond quickly, if at all. Indeed, because its competitors are not required to make their services or fees public, and are not subject to a Commission determination of whether such services or fees are ''not unfairly discriminatory'' or equitably allocated, IDS is at a competitive disadvantage from the very start.

The Proposed Service and Fees

As noted above, the Exchange proposes to add to its rules a Wireless Fee Schedule setting forth the fees charged by IDS related to the Wireless Connections between the Mahwah data center and the Third Party Data Centers.

For each Wireless Connection, a customer would be charged a non-recurring initial charge and a monthly recurring charge (''MRC'') that would vary depending upon bandwidth and the location of the connection. The proposal would waive the first month's

[21] *See* Securities Exchange Act Release No. 62960 (September 21, 2010), 75 FR 59310 (September 27, 2010) (SR–NYSE–2010–56) (order approving a proposed rule change amending the price list to reflect fees charged for co-location services). As described by the Commission, co-location is when a ''trading center . . . rents rack space to market participants that enables them to place their servers in close physical proximity to a trading center's matching engine.'' 75 FR 3594, *supra* note 7, at 3610 (noting that ''[c]o-location helps minimize network and other types of latencies between the matching engine of trading centers and the servers of market participants'').

[22] *Id.*

[23] 15 U.S.C. 78f(b)(8).

MRC, to allow customers to test a new Wireless Connection for a month before incurring any MRCs, and the Exchange proposes to add text to the Wireless Fee Schedule accordingly. If a customer had an existing Wireless Connection and opted to upgrade or downgrade to a different size circuit connecting to the same Third Party Access Center, it would not be subject to the initial charge.

The Exchange proposes to establish the Wireless Fee Schedule with a section under the heading ''A. Wireless Connectivity'' setting forth the fees charged by IDS related to the Wireless Connections, as follows:

Type of service	Description	Amount of charge
Wireless Connection between Mahwah Data Center and Secaucus access center.	10 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $9,000.
Wireless Connection between Mahwah Data Center and Secaucus access center.	50 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $13,500.
Wireless Connection between Mahwah Data Center and Secaucus access center.	100 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $23,000.
Wireless Connection between Mahwah Data Center and Secaucus access center.	200 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $44,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	10 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $10,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	50 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $15,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	100 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $25,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	200 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $45,000.
Wireless Connections between (a) Mahwah Data Center and Carteret access center and (b) Mahwah Data Center and Secaucus Data Center.	50 Mb Circuits	$15,000 initial charge for both connections plus monthly charge for both connections of $22,000.
Wireless Connection between Mahwah Data Center and Markham access center.	1 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $6,000.
Wireless Connection between Mahwah Data Center and Markham access center.	5 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $15,500.
Wireless Connection between Mahwah Data Center and Markham access center.	10 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $23,000.

Proposed General Note

The Exchange and each of the Affiliate SROs are filing the Wireless Connections. Although each such market will have a Wireless Fee Schedule, a market participant that obtains a Wireless Connection will not be charged more than once for that service, irrespective of whether it is a member of one, some or none of the Exchange and the Affiliate SROs. Accordingly, the Exchange proposes that the Wireless Fee Schedule include a General Note that describes the billing practice for market participants, as follows:

A market participant that incurs fees from the New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc. or NYSE National, Inc. (collectively, the ''Affiliate SROs'') for a particular service pursuant to this Fee Schedule shall not be subject to fees for the same service charged by the other Affiliate SROs.

The proposed General Note would be consistent with the first general note in the co-location section of the Exchange and Affiliate SROs' price lists and fee schedule,[24] as well as the Nasdaq Stock Market rules.[25]

Application and Impact of the Proposed Change

The proposed change would apply to all market participants equally. The proposed change would not apply differently to distinct types or sizes of market participants. Market participants that require other types or sizes of network connections between the Mahwah data center and the Third Party Data Centers could still request them. The purchase of the service is completely voluntary and the Wireless Fee Schedule will be applied uniformly to all market participants.

Competitive Environment

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have additional options. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

Wireless connections involve beaming signals through the air between antennas that are within sight of one another. Because the signals travel a

[24] *See* Securities Exchange Act Release Nos. 70206 (August 15, 2013), 78 FR 51765 (August 21, 2013) (SR–NYSE–2013–59); 70176 (August 13, 2013), 78 FR 50471 (August 19, 2013) (SR–NYSEMKT–2013–67); 70173 (August 13, 2013), 78 FR 50459 (August 19, 2013) (SR–NYSEArca–2013–80); 83351 (May 31, 2018), 83 FR 26314 (June 6, 2018) (SR–NYSENAT–2018–07; and 87408 (October 28, 2019), 84 FR 58778 (November 1, 2019) (SR–NYSECHX–2019–12).

[25] *See, e.g.,* The Nasdaq Stock Market General Equity and Options Rules, General 8, Section 1.

straight, unimpeded line, and because light waves travel faster through air than through glass (fiber optics), wireless messages have lower latency than messages travelling through fiber optics. At the same time, as a general rule wireless networks have less uptime than fiber networks. Wireless networks are directly and immediately affected by adverse weather conditions, which can cause message loss and outage periods. Wireless networks cannot be configured with redundancy in the same way that fiber networks can. As a result, an equipment or weather issue at any one location on the network will cause the entire network to have an outage. In addition, maintenance can take longer than it would with a fiber based network, as the relevant tower may be in a hard to reach location, or weather conditions may present safety issues, delaying technicians servicing equipment. Even under normal conditions, a wireless network will have a higher error rate than a fiber network of the same length.

The proposed Wireless Connections traverse wireless connections through a series of towers equipped with wireless equipment, including, in the case of the Carteret and Secaucus connections, a pole on the grounds of the Mahwah data center. With the exception of the non-ICE entity that owns the wireless network used for the Wireless Connections to Secaucus and Carteret,[26] third parties do not have access to such pole. However, access to such pole is not required for third parties to establish wireless networks that can compete with the Wireless Connections to the Carteret and Secaucus Third Party Data Centers, as witnessed by the existing wireless connections offered by non-ICE entities currently serving market participants.

Proximity to a data center is not the only determinant of a wireless network's latency. Rather, the latency of a wireless network depends on several factors. Variables include the wireless equipment utilized; the route of, and number of towers or buildings in, the network; and the fiber equipment used at either end of the connection. Moreover, latency is not the only consideration that a market participant may have in selecting a wireless network. Other considerations may include the bandwidth of the offered connection; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

2. Statutory Basis

Although the Exchange does not believe that the present proposed change is a change to the ''rules of an exchange'' [27] required to be filed with the Commission under the Act, the Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[28] in general, and furthers the objectives of Section 6(b)(5) of the Act,[29] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and does not unfairly discriminate between customers, issuers, brokers, or dealers. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[30] 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

The Exchange believes its proposal is reasonable.

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham.

The Wireless Connections provide market participants with one means of connectivity, but substitute products are available, as witnessed by the existing wireless connections offered by non-ICE entities currently serving market participants. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

Market participants' considerations in determining what connectivity to purchase may include latency; bandwidth size; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange believes that the proposed pricing for the Wireless Connections is reasonable because it allows market participants to select the connectivity options that best suit their needs. A market participant that opts to connect with a Wireless Network would be able to select the route and bandwidth that better suit its needs, thereby helping it tailor its operations to the requirements of its business operations. The fees also reflect the benefit received by customers in terms of lower latency over the fiber optics options.

Only market participants that voluntarily select to receive Wireless Connections are charged for them, and those services are available to all market participants. Furthermore, the Exchange believes that the services and fees proposed herein are reasonable because, in addition to the services being completely voluntary, they are available to all market participants on an equal basis (*i.e.,* the same products and services are available to all market participants). All market participants that voluntarily select Wireless Connections would be charged the same amount for the same services and would have their first month's MRC for Wireless Connections waived.

Overall, the Exchange believes that the proposed change is reasonable because the Wireless Connections described herein are offered as a convenience to market participants, but offering them requires the provision,

[26] *See* note 19, *supra.*

[27] *See* 15 U.S.C. 78c(a)(27) (defining the term ''rules of an exchange'').

[28] 15 U.S.C. 78f(b).

[29] 15 U.S.C. 78f(b)(5).

[30] 15 U.S.C. 78f(b)(4).

maintenance and operation of the Mahwah data center, wireless networks and access centers in the Third Party Data Centers, including the installation and monitoring, support and maintenance of the services.

The Exchange believes that the proposed waiver of the first month's MRC is reasonable as it would allow customers to test a Wireless Connection for a month before incurring any monthly recurring fees and may act as an incentive to market participants to connect to a Wireless Connection. The Exchange believes that the proposed waiver of the initial charge if a customer has an existing Wireless Connection and opted to upgrade or downgrade to a different size circuit at the same Third Party Data Center is reasonable because the change in Wireless Connection would not require IDS to do any physical work to implement the connection.

The Exchange believes that its proposed General Note is reasonable because it would provide transparency regarding how the billing practice for Wireless Connections functions. The Exchange believes that a customer should not be charged more than once for a Wireless Connection. For example, to charge one customer twice for a Wireless Connection because that customer is a member of two Affiliate SROs, and so subject to the rules of both Affiliate SROs, when another customer that buys the same Wireless Connection only pays once, would not promote just and equitable principles of trade, and could result in the Exchanges and Affiliate SROs receiving the proceeds from multiple fees despite only providing a service once.

The Proposed Change Is an Equitable Allocation of Fees and Credits

The Exchange believes its proposal equitably allocates its fees among its market participants.

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all market participants equally. As is currently the case, the purchase of any connectivity service is completely voluntary and the Wireless Fee Schedule will be applied uniformly to all customers.

Without this proposed rule change, market participants seeking connectivity to a Third Party Data Center would have fewer options. With it, because the Wireless Connections are offered at different bandwidths and price points, market participants have more choices with respect to the form and price of the connectivity they use, allowing a market participant that opts to connect with a wireless network to select the connectivity and bandwidth that better suit its needs, thereby helping it tailor its operations to the requirements of its business operations.

The Exchange believes that its proposed General Note is equitable because a customer would not be charged more than once for a Wireless Connection. For example, to charge one customer twice for a Wireless Connection because that customer is a member of two Affiliate SROs, and so subject to the rules of both Affiliate SROs, when another customer that buys the same Wireless Connection only pays once, would not promote just and equitable principles of trade, and could result in the Exchanges and Affiliate SROs receiving the proceeds from multiple fees despite only providing a service once. The Exchange believes that its proposed General Note is reasonable because it would provide transparency regarding how the billing practice for Wireless Connections functions.

The Proposed Change Is Not Unfairly Discriminatory

The Exchange believes its proposal is not unfairly discriminatory.

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all market participants equally. As is currently the case, the purchase of any connectivity service is completely voluntary and the Wireless Fee Schedule will be applied uniformly to all customers.

Without this proposed rule change, market participants seeking connectivity to a Third Party Data Center would have fewer options. With it, because the Wireless Connections are offered at different bandwidths and price points, market participants have more choices with respect to the form and price of the connectivity they use, allowing a market participant that opts to connect with a wireless network to select the connectivity and bandwidth that better suit its needs, thereby helping it tailor its operations to the requirements of its business operations.

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have additional options. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

Market participants' considerations in determining what connectivity to purchase may include latency; bandwidth size; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange believes that its proposed General Note would not be unfairly discriminatory because a customer would not be charged more than once for a Wireless Connection. For example, to charge one customer twice for a Wireless Connection because that customer is a member of two Affiliate SROs, and so subject to the rules of both Affiliate SROs, when another customer that buys the same Wireless Connection only pays once, would not promote just and equitable principles of trade, and could result in the Exchanges and Affiliate SROs receiving the proceeds from multiple fees despite only providing a service once.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the only burden on competition of the proposed change is on IDS and other commercial connectivity providers. Solely because IDS is wholly owned by the same parent company as the Exchange, IDS will be at a competitive disadvantage to its commercial competitors, and its commercial competitors, without a filing requirement, will be at a relative competitive advantage to IDS.

By permitting IDS to continue to offer the Wireless Connectivity, approval of the proposed changes would contribute to competition by allowing IDS to compete with other connectivity providers, and thus provides market participants another connectivity option. For this reason, the proposed rule changes will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[31]

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham. Importantly, the Exchange does not control the Third Party Data Centers and could not preclude other parties from creating new wireless or fiber connections to any of the Third Party Data Centers.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have additional options. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The proposed Wireless Connections traverse wireless connections through a series of towers equipped with wireless equipment, including, in the case of the Carteret and Secaucus connections, a pole on the grounds of the Mahwah data center. With the exception of the non-ICE entity that owns the wireless network used for the Wireless Connections to Secaucus and Carteret,[32] third parties do not have access to such pole, as the IDS wireless network has exclusive rights to operate wireless equipment on the Mahwah data center pole. IDS does not sell rights to third parties to operate wireless equipment on the pole, due to space limitations, security concerns, and the interference that would arise between equipment placed too closely together.

Access to the pole or roof is not required for other parties to establish wireless networks that can compete with the Wireless Connections, as witnessed by the existing wireless connections offered by non-ICE entities currently serving market participants. The latency of a wireless network depends on several factors, not just proximity to a data center. Variables include the wireless equipment utilized; the route of, and number of towers or buildings in, the network; and the fiber equipment used at either end of the connection. In addition, latency is not the only consideration that a market participant may have in selecting a wireless network. Market participants' considerations in determining what connectivity to purchase may include latency; bandwidth size; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions.

The Exchange operates in a highly competitive market in which exchanges and other vendors offer connectivity options between data centers as a means to facilitate the trading and other market activities of market participants. 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 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.'' [33]

The proposed change does not affect competition among national securities exchanges or among members of the Exchange, but rather between IDS and its commercial competitors.

For the reasons described above, the Exchange believes that the proposed rule changes reflect this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or 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 the 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–NYSE–2020–05 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2020–05. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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

[31] 15 U.S.C. 78f(b)(8).

[32] *See* note 19, *supra.*

[33] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, at 37499 (June 29, 2005).

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–NYSE–2020–05, and should be submitted on or before March 10, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–03095 Filed 2–14–20; 8:45 am]

BILLING CODE 8011–01–P

[34] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88169; File No. SR–NYSEAMER–2020–05]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing of Proposed Rule Change To Establish a Schedule of Wireless Connectivity Fees and Charges With Wireless Connections

February 11, 2020.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on January 30, 2020, NYSE American LLC (''NYSE American'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish a schedule of Wireless Connectivity Fees and Charges (the ''Wireless Fee Schedule'') with wireless connections between the Mahwah, New Jersey data center and other data centers. 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to establish the Wireless Fee Schedule with wireless connections between the Mahwah, New Jersey data center and three data centers that are owned and operated by third parties unaffiliated with the Exchange: (1) Carteret, New Jersey, (2) Secaucus, New Jersey, and (3) Markham, Canada (collectively, the ''Third Party Data Centers''). Market participants that purchase such a wireless connection (a ''Wireless Connection'') are charged an initial and monthly fee. In addition, the Exchange proposes to include a General Note to the Wireless Fee Schedule.

The Exchange does not believe that the present proposed change is a change to the ''rules of an exchange'' [4] required to be filed with the Commission under the Act. The definition of ''exchange'' under the Act includes ''the market facilities maintained by such exchange.'' [5] Based on its review of the relevant facts and circumstances, and as discussed further below, the Exchange has concluded that the Wireless Connections are not facilities of the Exchange within the meaning of the Act, and therefore do not need to be included in its rules.

The Exchange is making the current proposal solely because the Staff of the Commission has advised the Exchange that it believes the Wireless Connections are facilities of the Exchange and so must be filed as part of its rules.[6] The Staff has not set forth the basis of its conclusion beyond verbally noting that the Wireless Connections are provided by an affiliate of the Exchange and a market participant could use a Wireless Connection to trade on, or receive the market data of, the Exchange.[7]

The Exchange expects the proposed change to be operative 60 days after the present filing becomes effective.

The Exchange and the ICE Affiliates

To understand the Exchange's conclusion that the Wireless Connections are not facilities of the Exchange within the meaning of the Act, it is important to understand the very real distinction between the Exchange and its corporate affiliates (the ''ICE Affiliates''). The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Around the world, ICE operates seven regulated exchanges in addition to the Exchange and its four national securities exchange affiliates,[8] including futures markets, as

[4] *See* 15 U.S.C. 78c(a)(27) (defining the term ''rules of an exchange'').

[5] 15 U.S.C. 78c(a)(1). See 15 U.S.C. 78c(a)(2) (defining the term ''facility'' as applied to an exchange).

[6] Telephone conversation between Commission staff and representatives of the Exchange, December 12, 2019.

[7] *Id.* The Commission has previously stated that services were facilities of an exchange subject to the rule filing requirements without fully explaining its reasoning. In 2010, the Commission stated that exchanges had to file proposed rule changes with respect to co-location because ''[t]he Commission views co-location services as being a material aspect of the operation of the facilities of an exchange.'' The Commission did not specify why it reached that conclusion. *See* Securities Exchange Act Release No. 61358 (January 14, 2010), 75 FR 3594 (January 21, 2010) (concept release on equity market structure), at note 76.

In addition, in 2014, the Commission instituted proceedings to determine whether to disapprove a proposed rule change by The NASDAQ Stock Market LLC (''Nasdaq'') on the basis that Nasdaq's ''provision of third-party market data feeds to co-located clients appears to be an integral feature of its co-location program, and co-location programs are subject to the rule filing process.'' Securities Exchange Act Release No. 72654 (July 22, 2014), 79 FR 43808 (July 28, 2014) (SR–NASDAQ–2014–034). In its order, the Commission did not explain why it believed that the provision of third party data was an integral feature of co-location, or if it believed that it was a facility of Nasdaq, although the Nasdaq filing analyzed each prong of the definition of facility in turn. *See* Securities Exchange Act Release No. 71990 (April 22, 2014), 79 FR 23389 (April 28, 2014) (SR–NASDAQ–2014–034).

[8] The Exchange's four national securities exchange affiliates are the New York Stock Exchange LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc. (together, the ''Affiliate SROs'').

well as six clearing houses. Among others, the ICE Affiliates are subject to the jurisdiction of regulators in the U.S., U.K., E.U., the Netherlands, Canada and Singapore.[9] In all, the ICE Affiliates include hundreds of ICE subsidiaries, including more than thirty that are significant legal entity subsidiaries as defined by Commission rule.[10]

Through its ICE Data Services (''IDS'') business,[11] ICE operates the ICE Global Network (''IGN''), a global connectivity network whose infrastructure provides access to over 150 global markets, including the Exchange and Affiliate SROs, and over 750 data sources. All the ICE Affiliates are ultimately controlled by ICE, as the indirect parent company, but generally they do not control each other. In the present case, it is IDS, not the Exchange, that provides the Wireless Connections to market participants. The Exchange does not control IDS.

Wireless Connections

If a market participant wants a connection between one of the Third Party Data Centers and the Mahwah data center, it may opt to purchase a Wireless Connection, for which it will be charged an initial and monthly fee.

Once requested, IDS establishes a Wireless Connection between the IDS equipment in the Third Party Data Center and IDS equipment in the Mahwah data center. IDS contracts with a non-ICE entity to provide the Wireless Connections between the Secaucus and Carteret Third Party Data Centers and the Mahwah data center, through a series of towers equipped with wireless equipment. IDS uses its own wireless network for the Wireless Connection between the Markham Third Party Data Center and the Mahwah data center. At either end of the Wireless Connection, the customer uses a cross connect or other cable to connect its own equipment to the IDS equipment.[12] In the Mahwah data center, the cross connect leads to the customer's server in co-location.

The Wireless Connection does not connect to the Exchange trading and execution systems, nor is it a system of communication from the customer's server in co-location to the trading and execution systems of the Exchange or the Affiliate SROs (collectively, the ''SRO Systems''). Rather, a Wireless Connection facilitates the customer's interaction with itself. Essentially, a Wireless Connection is an empty pipe that a customer can use to communicate between its equipment in co-location and its equipment in the Third Party Data Center.

Customers have control over the data they send over their Wireless Connections. They may, but are not required to, use them to send trading orders to their equipment in co-location; relay Exchange market data, third party market data and public quote feeds from Securities Information Processors; send risk management, billing, or compliance information to their preferred location; or to carry any other market information or other data they wish to and from their equipment in the Third Party Data Centers and Mahwah data center. The Exchange does not, and cannot, know what data customers send over the Wireless Connections. The Exchange does not send or receive any data over the Wireless Connections.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have options. There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Carteret and Secaucus Third Party Data Centers using wireless equipment installed on towers and buildings near the Mahwah data center. Some market participants have their own proprietary wireless networks. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

The Wireless Connections Are Not Facilities of the Exchange

The Definition of ''Exchange''

The definition of ''exchange'' focuses on the exchange entity and what it does:[13]

> The term ''exchange'' means any organization, association, or group of persons, whether incorporated or unincorporated, which constitutes, maintains, or provides a market place or facilities for bringing together purchasers and sellers of securities or for otherwise performing with respect to securities the functions commonly performed by a stock exchange as that term is generally understood, and includes the market place and the market facilities maintained by such exchange.

If the ''exchange'' definition included all of an exchange's affiliates, the ''Exchange'' would encompass a global network of futures markets, clearing houses, and data providers, and all of those entities worldwide would be subject to regulation by the Commission. That, however, is not what the definition in the Act provides.

The Exchange and the Affiliate SROs fall squarely within the Act's definition of an ''exchange'': They each provide a market place to bring together purchasers and sellers of securities and perform with respect to securities the functions commonly performed by a stock exchange.

That is not true for the non-exchange ICE Affiliates. Those ICE Affiliates do not provide such a marketplace or perform ''with respect to securities the functions commonly performed by a stock exchange,'' and therefore they are not an ''exchange'' or part of the ''Exchange'' for purposes of the Act. Accordingly, in conducting its analysis, the Exchange does not automatically collapse the ICE Affiliates into the Exchange. The Wireless Connections are also not part of the Exchange, as they are services, and as such cannot be part of an ''organization, association or group of persons'' with the Exchange.

In Rule 3b–16 the Commission further defined the term ''exchange'' under the Act, stating that:[14]

> (a) An organization, association, or group of persons shall be considered to constitute, maintain, or provide ''a market place or facilities for bringing together purchasers and sellers of securities or for otherwise performing with respect to securities the functions commonly performed by a stock exchange,'' as those terms are used in *section* 3(a)(1) of the Act . . . if such organization, association, or group of persons:
>
> (1) Brings together the orders for securities of multiple buyers and sellers; and
>
> (2) Uses established, non-discretionary methods (whether by providing a trading facility or by setting rules) under which such orders interact with each other, and the buyers and sellers entering such orders agree to the terms of a trade.

The non-exchange ICE Affiliates do not bring ''together orders for securities of multiple buyers and sellers,'' and so are not an ''exchange'' or part of the ''Exchange'' for purposes of Rule 3b–16.

The relevant question, then, is whether the Wireless Connections are ''facilities'' of the Exchange.

[9] Intercontinental Exchange, Inc. Annual Report on Form 10–K for the year ended December 31, 2018, Exhibit 21.1 (filed February 7, 2019), at 15–16.

[10] *Id.* at Exhibit 21.1.

[11] The IDS business operates through several different ICE Affiliates, including NYSE Technologies Connectivity, Inc., an indirect subsidiary of the NYSE.

[12] A cable connects the IDS and customer equipment in the Markham Third Party Data Center. Elsewhere, the customer buys a cross connect from IDS. The cross connects utilized in the Mahwah data center are filed with the Commission. *See* Securities Exchange Act Release No. 67665 (August 15, 2012), 77 FR 50734 (August 22, 2012) (SR–NYSEMKT–2012–11).

[13] 15 U.S.C. 78c(a)(1).

[14] 17 CFR 240.3b–16(a).

The Definition of ''Facility''

The Act defines a ''facility'' [15] as follows:

> The term ''facility'' when used with respect to an exchange includes [1] its premises, [2] tangible or intangible property whether on the premises or not, [3] any right to the use of such premises or property or any service thereof for the purpose of effecting or reporting a transaction on an exchange (including, among other things, any system of communication to or from the exchange, by ticker or otherwise, maintained by or with the consent of the exchange), and [4] any right of the exchange to the use of any property or service.

In 2015 the Commission noted that whether something is a ''facility'' is not always black and white, as ''any determination as to whether a service or other product is a facility of an exchange requires an analysis of the particular facts and circumstances.'' [16] Accordingly, the Exchange understands that the specific facts and circumstances of the Wireless Connections must be assessed before a determination can be made regarding whether or not they are facilities of the Exchange.[17]

The first prong of the definition is that ''facility,'' when used with respect to an exchange, includes ''its premises.'' That prong is not applicable in this case, because the Wireless Connections are not premises of the Exchange. The term ''premises'' is generally defined as referring to an entity's building, land, and appurtenances.[18] The wireless network that runs between IDS equipment in the Mahwah data center and IDS equipment in Third Party Data Centers, much of which is actually owned, operated and maintained by a non-ICE entity,[19] does not connect to the Exchange trading and execution systems and is not the premises of the Exchange. The portion of the Mahwah data center where the ''exchange'' functions are performed—*i.e.* the SRO Systems that bring together purchasers and sellers of securities and perform with respect to securities the functions commonly performed by a stock exchange—could be construed as the ''premises'' of the Exchange, but the same is not true for a wireless network that is almost completely outside of the Mahwah data center.

The second prong of the definition of ''facility'' provides that a facility includes the exchange's ''tangible or intangible property whether on the premises or not.'' The Wireless Connections are not the property of the Exchange: They are services. The underlying wireless network is owned by ICE Affiliates and a non-ICE entity. As noted, the Act does not automatically collapse affiliates into the definition of an ''exchange.'' A review of the facts set forth above shows that there is a real distinction between the Exchange and its ICE Affiliates with respect to the Wireless Connections, and so something owned by an ICE Affiliate is not owned by the Exchange.

The third prong of the definition of ''facility'' provides that a facility includes

> any right to the use of such premises or property or any service thereof for the purpose of effecting or reporting a transaction on an exchange (including, among other things, any system of communication to or from the exchange, by ticker or otherwise, maintained by or with the consent of the exchange).[20]

This prong does not capture the Wireless Connections because the Exchange does not have the right to use the Wireless Connections to effect or report a transaction on the Exchange. ICE Affiliates and a non-ICE entity own and maintain the wireless network underlying the Wireless Connections, and ICE Affiliates, not the Exchange, offer and provide the Wireless Connections to customers. The Exchange does not know whether or when a market participant has entered into an agreement for a Wireless Connection and has no right to approve or disapprove of the provision of a Wireless Connection, in the same way that the Exchange would have no right to approve or disapprove of the provision of connectivity to a market participant in co-location or elsewhere by any other provider. The Exchange does not put content onto the Wireless Connections. When a customer terminates a Wireless Connection, the Exchange does not consent to the termination.

The Wireless Connections do not connect to the Exchange trading and execution systems. As such, the Wireless Connections are not provided for ''the purpose of effecting or reporting a transaction on'' the Exchange. Rather, a Wireless Connection facilitates the customer's interaction with itself. Each Wireless Connection connects the IDS equipment in the Third Party Data Center and IDS equipment in the Mahwah data center. At either end of the Wireless Connection, the customer uses a cross connect or other cable to connect its own equipment to the IDS equipment. In the Mahwah data center, the cross connect leads to the customer's server in co-location, not the Exchange trading and execution systems.

It is important to remember that the customers' equipment in the Mahwah data center is not provided by, part of, or a facility of, the Exchange. The Exchange provides the space in which customers' equipment is housed, and permits customers to use their equipment to communicate with the SRO Systems through services, such as connections to the local area networks, that are filed with the Commission.[21] The Exchange provides the space, but not the equipment. Accordingly, even if a customer were to use a Wireless Connection to send instructions to trade or to receive a report of a trade, the customer would not be sending instructions to the Exchange, but rather to its own equipment.

The Exchange believes the example in the parenthetical in the third prong of the definition of ''facility'' cannot be read as an independent prong of the definition. Such a reading would ignore that the parentheses and the word ''including'' clearly indicate that ''any system of communication to or from an exchange . . . maintained by or with

[15] 15 U.S.C. 78c(a)(2).

[16] Securities Exchange Act Release No. 76127 (October 9, 2015), 80 FR 62584 (October 16, 2015) (SR–NYSE–2015–36), at note 9 (order approving proposed rule change amending Section 907.00 of the Listed Company Manual). *See also* 79 FR 23389, *supra* note 7, at note 4 (noting that that the definition of the term ''facility'' has not changed since it was originally adopted) and 23389 (stating that the SEC ''has not separately interpreted the definition of 'facility'").

[17] As with the definition of ''exchange,'' the ICE Affiliates do not automatically fall within the definition of a ''facility.'' The definition focuses on ownership and the right to use properties and services, not corporate relationships. Indeed, if the term ''exchange'' in the definition of a facility included ''an exchange and its affiliates,'' then the rest of the functional prongs of the facility definition would be meaningless. Fundamental rules of statutory construction dictate that statutes be interpreted to give effect to each of their provisions, so as not to render sections of the statute superfluous.

[18] *See, e.g.,* definition of ''premises'' in Miriam-Webster Dictionary, at *https://www.merriam-webster.com/dictionary/premises,* and Cambridge English Dictionary, at *https://dictionary.cambridge.org/us/dictionary/english/premises.*

[19] A non-ICE entity owns, operates and maintains the wireless network between the Mahwah data center and the Carteret and Secaucus Third Party Data Centers pursuant to an agreement between the non-ICE entity and an ICE Affiliate.

[20] 15 U.S.C. 78c(a)(2).

[21] *See* Securities Exchange Act Release No. 62961 (September 21, 2010), 75 FR 59299 (September 27, 2010) (SR–NYSEAmex–2010–80) order approving a proposed rule change amending the price list to reflect fees charged for co-location services). As described by the Commission, co-location is when a ''trading center . . . rents rack space to market participants that enables them to place their servers in close physical proximity to a trading center's matching engine.'' 75 FR 3594, *supra* note 7, at 3610 (noting that ''[c]o-location helps minimize network and other types of latencies between the matching engine of trading centers and the servers of market participants'').

the consent of the exchange'' is explaining the preceding text. By its terms, the parenthetical is providing a non-exclusive example of the type of property or service to which the prong refers, and does not remove the requirement that there must be a right to use the premises, property or service to effect or report a transaction on an exchange. It is making sure the reader understands that ''facility'' includes a ticker system that an exchange has the right to use, not creating a new fifth prong to the definition. In fact, if the ''right to use'' requirement were ignored, every communication provider that connected to an exchange, including any broker-dealer system and telecommunications network, would become a facility of that exchange so long as the exchange consented to the connection, whether or not the connection was used to trade or report a trade, and whether or not the exchange had any right at all to the use of the connection.

The fourth prong of the definition provides that a facility includes ''any right of the exchange to the use of any property or service.'' [22] As described above, the Exchange does not have the right to use the Wireless Connections. Instead, the customers of the Wireless Connections are customers who enter into an agreement with ICE Affiliates for connections over a wireless network, much of which is owned, operated and maintained by a non-ICE entity.

Accordingly, for all the reasons discussed above, the Wireless Connections provided by ICE Affiliates are not facilities of the Exchange.

The legal conclusion that the Wireless Connections are not facilities of the Exchange is strongly supported by the facts. The Wireless Connections are neither necessary for, nor integrally connected to, the operations of the Exchange. They are empty pipes that customers can use as they like. In this context, IDS simply acts as a vendor selling connectivity, just like the other vendors that offer wireless connections in the Carteret and Secaucus Third Party Data Centers and fiber connections to all the Third Party Data Centers. The fact that in this case it is ICE Affiliates that offer the Wireless Connections does not make the Wireless Connections facilities of the Exchange any more than are the connections offered by other parties.

Further, the Exchange believes that requiring it to file this proposed rule change is not necessary in order for the Commission to ensure that the Exchange is satisfying its requirements under the Act. Because, as described above, the Wireless Connections are not necessary for, nor connected to, the operations of the Exchange, and customers are not required to use the Wireless Connections, holding the Wireless Connections to the statutory standards in Section 6(b) serves no purpose.

Instead, the sole impact of the requirement that the Exchange file the Wireless Connections is to place an undue burden on competition on the ICE Affiliates that offer the connections, compared to their market competitors. This filing requirement, thus, itself is inconsistent with the requirement under Section 6(b)(8) of the Act that the rules of the exchange not ''impose any burden on competition not necessary or appropriate in furtherance of the purposes of [the Act].'' [23] This burden on competition arises because IDS would be unable, for example, to offer a client or potential client a different bandwidth it requests, without the delay and uncertainty of a filing, but its competitors will. Similarly, if a competitor decides to undercut IDS' fees because IDS, unlike the competitor, has to make its fees public, IDS will not be able to respond quickly, if at all. Indeed, because its competitors are not required to make their services or fees public, and are not subject to a Commission determination of whether such services or fees are ''not unfairly discriminatory'' or equitably allocated, IDS is at a competitive disadvantage from the very start.

The Proposed Service and Fees

As noted above, the Exchange proposes to add to its rules a Wireless Fee Schedule setting forth the fees charged by IDS related to the Wireless Connections between the Mahwah data center and the Third Party Data Centers.

For each Wireless Connection, a customer would be charged a non-recurring initial charge and a monthly recurring charge (''MRC'') that would vary depending upon bandwidth and the location of the connection. The proposal would waive the first month's MRC, to allow customers to test a new Wireless Connection for a month before incurring any MRCs, and the Exchange proposes to add text to the Wireless Fee Schedule accordingly. If a customer had an existing Wireless Connection and opted to upgrade or downgrade to a different size circuit connecting to the same Third Party Access Center, it would not be subject to the initial charge.

The Exchange proposes to establish the Wireless Fee Schedule with a section under the heading ''A. Wireless Connectivity'' setting forth the fees charged by IDS related to the Wireless Connections, as follows:

Type of service	Description	Amount of charge
Wireless Connection between Mahwah Data Center and Secaucus access center.	10 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $9,000.
Wireless Connection between Mahwah Data Center and Secaucus access center.	50 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $13,500.
Wireless Connection between Mahwah Data Center and Secaucus access center.	100 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $23,000.
Wireless Connection between Mahwah Data Center and Secaucus access center.	200 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $44,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	10 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $10,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	50 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $15,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	100 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $25,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	200 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $45,000.
Wireless Connections between (a) Mahwah Data Center and Carteret access center and (b) Mahwah Data Center and Secaucus Data Center.	50 Mb Circuits	$15,000 initial charge for both connections plus monthly charge for both connections of $22,000.

[22] *Id.*

[23] 15 U.S.C. 78f(b)(8).

Type of service	Description	Amount of charge
Wireless Connection between Mahwah Data Center and Markham access center.	1 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $6,000.
Wireless Connection between Mahwah Data Center and Markham access center.	5 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $15,500.
Wireless Connection between Mahwah Data Center and Markham access center.	10 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $23,000.

Proposed General Note

The Exchange and each of the Affiliate SROs are filing the Wireless Connections. Although each such market will have a Wireless Fee Schedule, a market participant that obtains a Wireless Connection will not be charged more than once for that service, irrespective of whether it is a member of one, some or none of the Exchange and the Affiliate SROs. Accordingly, the Exchange proposes that the Wireless Fee Schedule include a General Note that describes the billing practice for market participants, as follows:

A market participant that incurs fees from the New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc. or NYSE National, Inc. (collectively, the ''Affiliate SROs'') for a particular service pursuant to this Fee Schedule shall not be subject to fees for the same service charged by the other Affiliate SROs.

The proposed General Note would be consistent with the first general note in the co-location section of the Exchange and Affiliate SROs' price lists and fee schedule,[24] as well as the Nasdaq Stock Market rules.[25]

Application and Impact of the Proposed Change

The proposed change would apply to all market participants equally. The proposed change would not apply differently to distinct types or sizes of market participants. Market participants that require other types or sizes of network connections between the Mahwah data center and the Third Party Data Centers could still request them. The purchase of the service is completely voluntary and the Wireless Fee Schedule will be applied uniformly to all market participants.

Competitive Environment

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have additional options. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

Wireless connections involve beaming signals through the air between antennas that are within sight of one another. Because the signals travel a straight, unimpeded line, and because light waves travel faster through air than through glass (fiber optics), wireless messages have lower latency than messages travelling through fiber optics. At the same time, as a general rule wireless networks have less uptime than fiber networks. Wireless networks are directly and immediately affected by adverse weather conditions, which can cause message loss and outage periods. Wireless networks cannot be configured with redundancy in the same way that fiber networks can. As a result, an equipment or weather issue at any one location on the network will cause the entire network to have an outage. In addition, maintenance can take longer than it would with a fiber based network, as the relevant tower may be in a hard to reach location, or weather conditions may present safety issues, delaying technicians servicing equipment. Even under normal conditions, a wireless network will have a higher error rate than a fiber network of the same length.

The proposed Wireless Connections traverse wireless connections through a series of towers equipped with wireless equipment, including, in the case of the Carteret and Secaucus connections, a pole on the grounds of the Mahwah data center. With the exception of the non-ICE entity that owns the wireless network used for the Wireless Connections to Secaucus and Carteret,[26] third parties do not have access to such pole. However, access to such pole is not required for third parties to establish wireless networks that can compete with the Wireless Connections to the Carteret and Secaucus Third Party Data Centers, as witnessed by the existing wireless connections offered by non-ICE entities currently serving market participants.

Proximity to a data center is not the only determinant of a wireless network's latency. Rather, the latency of a wireless network depends on several factors. Variables include the wireless equipment utilized; the route of, and number of towers or buildings in, the network; and the fiber equipment used at either end of the connection. Moreover, latency is not the only consideration that a market participant may have in selecting a wireless network. Other considerations may include the bandwidth of the offered connection; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

2. Statutory Basis

Although the Exchange does not believe that the present proposed change is a change to the ''rules of an

[24] *See* Securities Exchange Act Release Nos. 70206 (August 15, 2013), 78 FR 51765 (August 21, 2013) (SR–NYSE–2013–59); 70176 (August 13, 2013), 78 FR 50471 (August 19, 2013) (SR–NYSEMKT–2013–67); 70173 (August 13, 2013), 78 FR 50459 (August 19, 2013) (SR–NYSEArca–2013–80); 83351 (May 31, 2018), 83 FR 26314 (June 6, 2018) (SR–NYSENAT–2018–07; and 87408 (October 28, 2019), 84 FR 58778 (November 1, 2019) (SR–NYSECHX–2019–12).

[25] *See, e.g.,* The Nasdaq Stock Market General Equity and Options Rules, General 8, Section 1.

[26] *See* note 19, *supra.*

exchange'' [27] required to be filed with the Commission under the Act, the Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[28] in general, and furthers the objectives of Section 6(b)(5) of the Act,[29] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and does not unfairly discriminate between customers, issuers, brokers, or dealers. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[30] 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

The Exchange believes its proposal is reasonable.

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham.

The Wireless Connections provide market participants with one means of connectivity, but substitute products are available, as witnessed by the existing wireless connections offered by non-ICE entities currently serving market participants. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

Market participants' considerations in determining what connectivity to purchase may include latency; bandwidth size; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange believes that the proposed pricing for the Wireless Connections is reasonable because it allows market participants to select the connectivity options that best suit their needs. A market participant that opts to connect with a Wireless Network would be able to select the route and bandwidth that better suit its needs, thereby helping it tailor its operations to the requirements of its business operations. The fees also reflect the benefit received by customers in terms of lower latency over the fiber optics options.

Only market participants that voluntarily select to receive Wireless Connections are charged for them, and those services are available to all market participants. Furthermore, the Exchange believes that the services and fees proposed herein are reasonable because, in addition to the services being completely voluntary, they are available to all market participants on an equal basis (*i.e.,* the same products and services are available to all market participants). All market participants that voluntarily select Wireless Connections would be charged the same amount for the same services and would have their first month's MRC for Wireless Connections waived.

Overall, the Exchange believes that the proposed change is reasonable because the Wireless Connections described herein are offered as a convenience to market participants, but offering them requires the provision, maintenance and operation of the Mahwah data center, wireless networks and access centers in the Third Party Data Centers, including the installation and monitoring, support and maintenance of the services.

The Exchange believes that the proposed waiver of the first month's MRC is reasonable as it would allow customers to test a Wireless Connection for a month before incurring any monthly recurring fees and may act as an incentive to market participants to connect to a Wireless Connection. The Exchange believes that the proposed waiver of the initial charge if a customer has an existing Wireless Connection and opted to upgrade or downgrade to a different size circuit at the same Third Party Data Center is reasonable because the change in Wireless Connection would not require IDS to do any physical work to implement the connection.

The Exchange believes that its proposed General Note is reasonable because it would provide transparency regarding how the billing practice for Wireless Connections functions. The Exchange believes that a customer should not be charged more than once for a Wireless Connection. For example, to charge one customer twice for a Wireless Connection because that customer is a member of two Affiliate SROs, and so subject to the rules of both Affiliate SROs, when another customer that buys the same Wireless Connection only pays once, would not promote just and equitable principles of trade, and could result in the Exchanges and Affiliate SROs receiving the proceeds from multiple fees despite only providing a service once.

The Proposed Change Is an Equitable Allocation of Fees and Credits

The Exchange believes its proposal equitably allocates its fees among its market participants.

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all market participants equally. As is currently the case, the purchase of any connectivity service is completely voluntary and the Wireless Fee Schedule will be applied uniformly to all customers.

Without this proposed rule change, market participants seeking connectivity to a Third Party Data Center would have fewer options. With it, because the Wireless Connections are offered at different bandwidths and price points, market participants have more choices with respect to the form and price of the connectivity they use, allowing a market participant that opts to connect with a wireless network to select the connectivity and bandwidth that better suit its needs, thereby helping it tailor its operations to the requirements of its business operations.

The Exchange believes that its proposed General Note is equitable because a customer would not be

[27] *See* 15 U.S.C. 78c(a)(27) (defining the term ''rules of an exchange'').

[28] 15 U.S.C. 78f(b).

[29] 15 U.S.C. 78f(b)(5).

[30] 15 U.S.C. 78f(b)(4).

charged more than once for a Wireless Connection. For example, to charge one customer twice for a Wireless Connection because that customer is a member of two Affiliate SROs, and so subject to the rules of both Affiliate SROs, when another customer that buys the same Wireless Connection only pays once, would not promote just and equitable principles of trade, and could result in the Exchanges and Affiliate SROs receiving the proceeds from multiple fees despite only providing a service once. The Exchange believes that its proposed General Note is reasonable because it would provide transparency regarding how the billing practice for Wireless Connections functions.

The Proposed Change Is Not Unfairly Discriminatory

The Exchange believes its proposal is not unfairly discriminatory.

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all market participants equally. As is currently the case, the purchase of any connectivity service is completely voluntary and the Wireless Fee Schedule will be applied uniformly to all customers.

Without this proposed rule change, market participants seeking connectivity to a Third Party Data Center would have fewer options. With it, because the Wireless Connections are offered at different bandwidths and price points, market participants have more choices with respect to the form and price of the connectivity they use, allowing a market participant that opts to connect with a wireless network to select the connectivity and bandwidth that better suit its needs, thereby helping it tailor its operations to the requirements of its business operations.

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have additional options. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

Market participants' considerations in determining what connectivity to purchase may include latency; bandwidth size; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange believes that its proposed General Note would not be unfairly discriminatory because a customer would not be charged more than once for a Wireless Connection. For example, to charge one customer twice for a Wireless Connection because that customer is a member of two Affiliate SROs, and so subject to the rules of both Affiliate SROs, when another customer that buys the same Wireless Connection only pays once, would not promote just and equitable principles of trade, and could result in the Exchanges and Affiliate SROs receiving the proceeds from multiple fees despite only providing a service once.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the only burden on competition of the proposed change is on IDS and other commercial connectivity providers. Solely because IDS is wholly owned by the same parent company as the Exchange, IDS will be at a competitive disadvantage to its commercial competitors, and its commercial competitors, without a filing requirement, will be at a relative competitive advantage to IDS.

By permitting IDS to continue to offer the Wireless Connectivity, approval of the proposed changes would contribute to competition by allowing IDS to compete with other connectivity providers, and thus provides market participants another connectivity option. For this reason, the proposed rule changes will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[31]

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham. Importantly, the Exchange does not control the Third Party Data Centers and could not preclude other parties from creating new wireless or fiber connections to any of the Third Party Data Centers.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have additional options. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The proposed Wireless Connections traverse wireless connections through a series of towers equipped with wireless equipment, including, in the case of the Carteret and Secaucus connections, a pole on the grounds of the Mahwah data center. With the exception of the non-ICE entity that owns the wireless network used for the Wireless Connections to Secaucus and Carteret,[32] third parties do not have access to such pole, as the IDS wireless network has exclusive rights to operate wireless equipment on the Mahwah data center pole. IDS does not sell rights to third parties to operate wireless equipment on the pole, due to space limitations,

[31] 15 U.S.C. 78f(b)(8).

[32] *See* note 19, *supra.*

security concerns, and the interference that would arise between equipment placed too closely together.

Access to the pole or roof is not required for other parties to establish wireless networks that can compete with the Wireless Connections, as witnessed by the existing wireless connections offered by non-ICE entities currently serving market participants. The latency of a wireless network depends on several factors, not just proximity to a data center. Variables include the wireless equipment utilized; the route of, and number of towers or buildings in, the network; and the fiber equipment used at either end of the connection. In addition, latency is not the only consideration that a market participant may have in selecting a wireless network. Market participants' considerations in determining what connectivity to purchase may include latency; bandwidth size; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions.

The Exchange operates in a highly competitive market in which exchanges and other vendors offer connectivity options between data centers as a means to facilitate the trading and other market activities of market participants. 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 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.'' [33]

The proposed change does not affect competition among national securities exchanges or among members of the Exchange, but rather between IDS and its commercial competitors.

For the reasons described above, the Exchange believes that the proposed rule changes reflect this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

[33] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, at 37499 (June 29, 2005).

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 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 the 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–NYSEAMER–2020–05 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2020–05. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2020–05, and should be submitted on or before March 10, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–03096 Filed 2–14–20; 8:45 am]

BILLING CODE 8011–01–P

[34] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88159; File No. SR–CboeBZX–2020–013]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule

February 11, 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 January 31, 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.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Equities Exchange (the ''Exchange'' or ''BZX Equities'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend its Fee Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule to amend the rate for liquidity adding orders that yield fee codes ''V'' [3] and ''Y''.[4] Additionally, the Exchange proposes to eliminate existing Add Volume Tier 1, Step-Up Tier 2, and Cross-Asset Add Volume Tiers 1 through 4. The Exchange also proposes to make corresponding changes to the numbering of the Add Volume Tiers and Step-Up Tiers.

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 13 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues that do not have similar self-regulatory responsibilities under the Exchange Act, to which market participants may direct their order flow. Based on publicly available information,[5] no single registered equities exchange has more than approximately 16% of the market share. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow.

The Exchange in particular operates a ''Maker-Taker'' model whereby it pays credits to Members that provide liquidity and assesses fees to those that remove liquidity. The Exchange's Fee Schedule sets forth the standard rebates and rates applied per share for orders that provide and remove liquidity, respectively. Particularly, for orders priced at or above $1.00, the Exchange provides a standard rebate of $0.0020 [6] to $0.0025 [7] per share for orders that add liquidity and assesses a fee of $0.0030 per share for orders that remove liquidity. 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.

Proposed Change To Amend Standard Rebate for Liquidity Adding Orders in Securities at or Above $1.00

The Exchange currently provides rebates for liquidity adding orders that yield fee codes ''V'' or ''Y'' of $0.0020 in securities priced at or above $1.00 in Tape A or C securities. Liquidity adding orders yielding fee code ''B'' [8] are provided a rebate of $0.0025 in securities priced at or above $1.00 in Tape B securities. The Exchange now proposes to increase the current rebate of $0.0020 per share to $0.0025 per share for orders yielding fee codes ''V'' and ''Y'' in securities priced at or above $1.00 in Tape A and Tape C securities. As the proposed rebate for orders yielding fee code ''V'' or ''Y'' is higher than the current rebate for such orders, the Exchange believes the proposed amendment will encourage Members to increase their liquidity on the Exchange.

Proposed Change To Eliminate Tier 1 of the Add Volume Tiers

In response to the competitive environment, the Exchange offers tiered pricing which provides Members opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met. Tiered pricing provides incremental incentives for Members to strive for higher or different tier levels by offering increasingly higher discounts or enhanced benefits for satisfying increasingly more stringent criteria or different criteria. For example, pursuant to footnote 1 of the Fee Schedule, the Exchange currently offers Tier 1 of the Add Volume Tiers which provides Members with a higher rebate of $0.0025 per share for liquidity adding orders yielding fee codes ''B'', ''V'', or ''Y'' when the Member has an ADAV [9] as a percentage of TCV [10] greater than or equal to 0.10%. Currently, orders yielding fee codes ''V'' and ''Y'' provide a standard rebate of $0.0020; however, the proposed amendment to fee codes ''V'' and ''Y'' would increase the standard rebate from $0.0020 to $0.0025. As a result, the rebate provided under Tier 1 would be equal to the proposed standard rebate of $0.0025 applicable to orders yielding fee codes ''V'' or ''Y'' and the existing standard rebate of $0.0025 applicable to orders yielding fee code ''B''. Therefore, the Exchange proposes to eliminate Tier 1 of the Add Volume Tiers and renumber the remaining tiers accordingly.

Proposed Change To Eliminate Cross-Asset Add Volume Tiers 1 Through 4 of the Add Volume Tiers

Footnote 1 of the Fee Schedule currently provides for the Cross-Asset Add Volume Tiers 1 through 4, which provide enhanced rebates ranging from $0.0028 to $0.0030 per share to Members meeting (1) a certain ADV [11] percentage as compared to the TCV on BZX Equities, and (2) certain liquidity adding option volume on the Cboe BZX Options Exchange (''BZX Options'') as compared to the OCV.[12] The Exchange adopted the Cross-Asset Add Volume Tiers to encourage Members to add liquidity on both BZX Equities and BZX Options. The Exchange now proposes to eliminate the four Cross-Asset Add Volume Tiers. Particularly, no Member has reached any of these tiers in several months and the Exchange therefore no

[3] ''V'' is appended to displayed orders that add liquidity to BZX Equities (Tape A).

[4] ''Y'' is appended to displayed orders that add liquidity to BZX Equities (Tape C).

[5] See Cboe Global Markets, U.S. Equities Market Volume Summary (January 29, 2020), available at *https://markets.cboe.com/us/equities/market_statistics/*.

[6] Displayed orders which add liquidity in Tape B securities receive a standard rebate of $0.0025 per share.

[7] Displayed orders which add liquidity in Tape A and C securities receive a standard rebate of $0.0020 per share.

[8] ''B'' is appended to displayed orders that add liquidity to BZX Equities (Tape B).

[9] ADAV means average daily volume calculated as the number of shares added per day. ADAV is calculated on a monthly basis.

[10] TCV means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply.

[11] ADV means average daily volume.

[12] OCC Customer Volume or ''OCV'' means the total equity and ETF options volume that clears in the Customer range at the Options Clearing Corporation (''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, using the definition of Customer as provided under the Exchange's Fee Schedule for BZX Options.

longer wishes to, nor is it required to, maintain such tiers.

Proposed Change To Eliminate Tier 2 of the Step-Up Tiers

Footnote 2 of the Fee Schedule currently provides for Tier 2 of the Step-Up Tiers, which provides an enhanced rebate of $0.0030 per share for Members with Step-Up Add TCV [13] from April 2016 equal to or greater than 0.15% and an ADAV as a percentage of TCV equal to or greater than 0.20%. The Exchange adopted Tier 2 of the Step-Up Tiers to encourage Members to grow their ADAV on the Exchange on a monthly basis from an April 2016 baseline. The Exchange now proposes to eliminate the Tier 2 of the Step-Up Tiers. Particularly, no Member has reached Tier 2 of the Step-Up Tiers in several months and the Exchange therefore no longer wishes to, nor is it required to, maintain such tier. The Exchange no longer believes Tier 2 is necessary and notes the Exchange is not required to maintain such an incentive program. Additionally, the Exchange proposes to re-number Step-Up Tiers 4 and 5 to reflect the elimination of Step-Up Tier 2.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[14] in general, and furthers the objectives of Section 6(b)(4),[15] 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 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. 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.

The Exchange operates in a highly-competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The proposed rule changes reflect a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members.

In particular, the Exchange believes the proposed amendment to increase the rebate for orders yielding fee codes ''V'' and ''Y'' from $0.0020 to $0.0025 is reasonable because it would uniformly provide a rebate of $0.0025 per share across Tape A, Tape B, and Tape C securities priced at or above $1.00. Further, the Exchange believes the proposed increased rebate will encourage additional order flow on the Exchange, which may result in greater liquidity to the benefit of all market participants on the Exchange by providing more trading opportunities. The Exchange also believes the proposed amendment to remove existing Tier 1 of the Add Volume Tiers is reasonable because the tier offers the same rebate as the proposed standard rebate for orders yielding fee codes ''V'' and ''Y'' and the existing standard rebate for orders yielding fee code ''B''. Therefore, existing Tier 1 of the Add Volume Tiers would provide no further incentive for Members to achieve an ADAV greater than or equal to 0.10% as a percentage of TCV. The Exchange believes the proposed changes are equitable and not unfairly discriminatory because they apply equally to all Members.

The Exchange believes eliminating the Cross-Asset Add Volume Tiers 1 through 4 and Step-Up Tier 2 is reasonable because the Exchange is not required to maintain these tiers and Members still have a number of other opportunities and a variety of ways to receive enhanced rebates, including the proposed enhanced standard rebate to orders yielding fee code ''V'' or ''Y''. Moreover, as noted above, no Member has achieved these tiers in several months. The Exchange believes the proposal to eliminate these tiers is also equitable and not unfairly discriminatory because it applies to all Members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on 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 displayed order flow to a public exchange, thereby promoting market depth, execution incentives and enhanced execution opportunities, as well as price discovery and transparency for all Members. As a result, the Exchange believes that the proposed 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.'' [16]

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 receive the enhanced standard rebate for orders yielding fee code ''V'' or ''Y''. Additionally the proposed change is designed to attract additional order flow to the Exchange. The Exchange believes that the modified standard rebate for orders yielding fee code ''V'' or ''Y'' would incentivize market participants to direct displayed liquidity and, as a result, executable order flow and improved price transparency, to the Exchange. Greater overall order flow and pricing transparency benefits all market participants on the Exchange by 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 other equities exchanges and off-exchange venues and alternative trading systems. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single equities exchange has more than approximately 16% of the market share.[17] 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

[13] ''Step-Up Add TCV'' means ADAV as a percentage of TCV in the relevant baseline month subtracted from current ADAV as a percentage of TCV.

[14] 15 U.S.C. 78f.

[15] 15 U.S.C. 78f(b)(4).

[16] Securities Exchange Act Release No. 51808, 70 FR 37495, 37498–99 (June 29, 2005) (S7–10–04) (Final Rule).

[17] *See supra* note 5.

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.'' [18] 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'. . . .''.[19] 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 has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from Members or other interested parties.

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) [20] of the Act and subparagraph (f)(2) of Rule 19b–4 [21] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

[18] See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[19] *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)).

[20] 15 U.S.C. 78s(b)(3)(A).

[21] 17 CFR 240.19b–4(f)(2).

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) [22] 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 No. SR–CboeBZX–2020–013 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 No. SR–CboeBZX–2020–013. 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 No. SR–CboeBZX–2020–013, and should be submitted on or before March 10, 2020.

[22] 15 U.S.C. 78s(b)(2)(B).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–03089 Filed 2–14–20; 8:45 am]

BILLING CODE 8011–01–P

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88170; File No. SR–NYSEArca–2020–08]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change To Establish a Schedule of Wireless Connectivity Fees and Charges With Wireless Connections

February 11, 2020.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on January 30, 2020, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish a schedule of Wireless Connectivity Fees and Charges (the ''Wireless Fee Schedule'') with wireless connections between the Mahwah, New Jersey data center and other data centers. The proposed change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to establish the Wireless Fee Schedule with wireless connections between the Mahwah, New Jersey data center and three data centers that are owned and operated by third parties unaffiliated with the Exchange: (1) Carteret, New Jersey, (2) Secaucus, New Jersey, and (3) Markham, Canada (collectively, the ''Third Party Data Centers''). Market participants that purchase such a wireless connection (a ''Wireless Connection'') are charged an initial and monthly fee. In addition, the Exchange proposes to include a General Note to the Wireless Fee Schedule.

The Exchange does not believe that the present proposed change is a change to the ''rules of an exchange'' [4] required to be filed with the Commission under the Act. The definition of ''exchange'' under the Act includes ''the market facilities maintained by such exchange.'' [5] Based on its review of the relevant facts and circumstances, and as discussed further below, the Exchange has concluded that the Wireless Connections are not facilities of the Exchange within the meaning of the Act, and therefore do not need to be included in its rules.

The Exchange is making the current proposal solely because the Staff of the Commission has advised the Exchange that it believes the Wireless Connections are facilities of the Exchange and so must be filed as part of its rules.[6] The Staff has not set forth the basis of its conclusion beyond verbally noting that the Wireless Connections are provided by an affiliate of the Exchange and a market participant could use a Wireless Connection to trade on, or receive the market data of, the Exchange.[7]

The Exchange expects the proposed change to be operative 60 days after the present filing becomes effective.

The Exchange and the ICE Affiliates

To understand the Exchange's conclusion that the Wireless Connections are not facilities of the Exchange within the meaning of the Act, it is important to understand the very real distinction between the Exchange and its corporate affiliates (the ''ICE Affiliates''). The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Around the world, ICE operates seven regulated exchanges in addition to the Exchange and its four national securities exchange affiliates,[8] including futures markets, as well as six clearing houses. Among others, the ICE Affiliates are subject to the jurisdiction of regulators in the U.S., U.K., E.U., the Netherlands, Canada and Singapore.[9] In all, the ICE Affiliates include hundreds of ICE subsidiaries, including more than thirty that are significant legal entity subsidiaries as defined by Commission rule.[10]

Through its ICE Data Services (''IDS'') business,[11] ICE operates the ICE Global Network (''IGN''), a global connectivity network whose infrastructure provides access to over 150 global markets, including the Exchange and Affiliate SROs, and over 750 data sources. All the ICE Affiliates are ultimately controlled by ICE, as the indirect parent company, but generally they do not control each other. In the present case, it is IDS, not the Exchange, that provides the Wireless Connections to market participants. The Exchange does not control IDS.

Wireless Connections

If a market participant wants a connection between one of the Third Party Data Centers and the Mahwah data center, it may opt to purchase a Wireless Connection, for which it will be charged an initial and monthly fee.

Once requested, IDS establishes a Wireless Connection between the IDS equipment in the Third Party Data Center and IDS equipment in the Mahwah data center. IDS contracts with a non-ICE entity to provide the Wireless Connections between the Secaucus and Carteret Third Party Data Centers and the Mahwah data center, through a series of towers equipped with wireless equipment. IDS uses its own wireless network for the Wireless Connection between the Markham Third Party Data Center and the Mahwah data center. At either end of the Wireless Connection, the customer uses a cross connect or other cable to connect its own equipment to the IDS equipment.[12] In the Mahwah data center, the cross connect leads to the customer's server in co-location.

The Wireless Connection does not connect to the Exchange trading and execution systems, nor is it a system of communication from the customer's server in co-location to the trading and execution systems of the Exchange or the Affiliate SROs (collectively, the ''SRO Systems''). Rather, a Wireless Connection facilitates the customer's interaction with itself. Essentially, a Wireless Connection is an empty pipe that a customer can use to communicate between its equipment in co-location

[4] *See* 15 U.S.C. 78c(a)(27) (defining the term ''rules of an exchange'').

[5] 15 U.S.C. 78c(a)(1). See 15 U.S.C. 78c(a)(2) (defining the term ''facility'' as applied to an exchange).

[6] Telephone conversation between Commission staff and representatives of the Exchange, December 12, 2019.

[7] *Id.* The Commission has previously stated that services were facilities of an exchange subject to the rule filing requirements without fully explaining its reasoning. In 2010, the Commission stated that exchanges had to file proposed rule changes with respect to co-location because ''[t]he Commission views co-location services as being a material aspect of the operation of the facilities of an exchange.'' The Commission did not specify why it reached that conclusion. *See* Securities Exchange Act Release No. 61358 (January 14, 2010), 75 FR 3594 (January 21, 2010) (concept release on equity market structure), at note 76.

In addition, in 2014, the Commission instituted proceedings to determine whether to disapprove a proposed rule change by The NASDAQ Stock Market LLC (''Nasdaq'') on the basis that Nasdaq's ''provision of third-party market data feeds to co-located clients appears to be an integral feature of its co-location program, and co-location programs are subject to the rule filing process.'' Securities Exchange Act Release No. 72654 (July 22, 2014), 79 FR 43808 (July 28, 2014) (SR–NASDAQ–2014–034). In its order, the Commission did not explain why it believed that the provision of third party data was an integral feature of co-location, or if it believed that it was a facility of Nasdaq, although the Nasdaq filing analyzed each prong of the definition of facility in turn. *See* Securities Exchange Act Release No. 71990 (April 22, 2014), 79 FR 23389 (April 28, 2014) (SR–NASDAQ–2014–034).

[8] The Exchange's four national securities exchange affiliates are the New York Stock Exchange LLC, NYSE American LLC, NYSE Chicago, Inc., and NYSE National, Inc. (together, the ''Affiliate SROs'').

[9] Intercontinental Exchange, Inc. Annual Report on Form 10–K for the year ended December 31, 2018, Exhibit 21.1 (filed February 7, 2019), at 15–16.

[10] *Id.* at Exhibit 21.1.

[11] The IDS business operates through several different ICE Affiliates, including NYSE Technologies Connectivity, Inc., an indirect subsidiary of the NYSE.

[12] A cable connects the IDS and customer equipment in the Markham Third Party Data Center. Elsewhere, the customer buys a cross connect from IDS. The cross connects utilized in the Mahwah data center are filed with the Commission. *See* Securities Exchange Act Release No. 67669 (August 15, 2012), 77 FR 50746 (August 22, 2012) (SR–NYSEArca–2012–62); and 67667 (August 15, 2012), 77 FR 50743 (August 22, 2012) (SR–NYSEArca–2012–63).

and its equipment in the Third Party Data Center.

Customers have control over the data they send over their Wireless Connections. They may, but are not required to, use them to send trading orders to their equipment in co-location; relay Exchange market data, third party market data and public quote feeds from Securities Information Processors; send risk management, billing, or compliance information to their preferred location; or to carry any other market information or other data they wish to and from their equipment in the Third Party Data Centers and Mahwah data center. The Exchange does not, and cannot, know what data customers send over the Wireless Connections. The Exchange does not send or receive any data over the Wireless Connections.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have options. There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Carteret and Secaucus Third Party Data Centers using wireless equipment installed on towers and buildings near the Mahwah data center. Some market participants have their own proprietary wireless networks. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

The Wireless Connections Are Not Facilities of the Exchange

The Definition of ''Exchange''

The definition of ''exchange'' focuses on the exchange entity and what it does: [13]

> The term ''exchange'' means any organization, association, or group of persons, whether incorporated or unincorporated, which constitutes, maintains, or provides a market place or facilities for bringing together purchasers and sellers of securities or for otherwise performing with respect to securities the functions commonly performed by a stock exchange as that term is generally understood, and includes the market place and the market facilities maintained by such exchange.

If the ''exchange'' definition included all of an exchange's affiliates, the ''Exchange'' would encompass a global network of futures markets, clearing houses, and data providers, and all of those entities worldwide would be subject to regulation by the Commission. That, however, is not what the definition in the Act provides.

The Exchange and the Affiliate SROs fall squarely within the Act's definition of an ''exchange'': They each provide a market place to bring together purchasers and sellers of securities and perform with respect to securities the functions commonly performed by a stock exchange.

That is not true for the non-exchange ICE Affiliates. Those ICE Affiliates do not provide such a marketplace or perform ''with respect to securities the functions commonly performed by a stock exchange,'' and therefore they are not an ''exchange'' or part of the ''Exchange'' for purposes of the Act. Accordingly, in conducting its analysis, the Exchange does not automatically collapse the ICE Affiliates into the Exchange. The Wireless Connections are also not part of the Exchange, as they are services, and as such cannot be part of an ''organization, association or group of persons'' with the Exchange.

In Rule 3b–16 the Commission further defined the term ''exchange'' under the Act, stating that: [14]

> (a) An organization, association, or group of persons shall be considered to constitute, maintain, or provide ''a market place or facilities for bringing together purchasers and sellers of securities or for otherwise performing with respect to securities the functions commonly performed by a stock exchange,'' as those terms are used in section 3(a)(1) of the Act . . . if such organization, association, or group of persons:
>
> (1) Brings together the orders for securities of multiple buyers and sellers; and
>
> (2) Uses established, non-discretionary methods (whether by providing a trading facility or by setting rules) under which such orders interact with each other, and the buyers and sellers entering such orders agree to the terms of a trade.

The non-exchange ICE Affiliates do not bring ''together orders for securities of multiple buyers and sellers,'' and so are not an ''exchange'' or part of the ''Exchange'' for purposes of Rule 3b–16.

The relevant question, then, is whether the Wireless Connections are ''facilities'' of the Exchange.

The Definition of ''Facility''

The Act defines a ''facility'' [15] as follows:

> The term ''facility'' when used with respect to an exchange includes [1] its premises, [2] tangible or intangible property whether on the premises or not, [3] any right to the use of such premises or property or any service thereof for the purpose of effecting or reporting a transaction on an exchange (including, among other things, any system of communication to or from the exchange, by ticker or otherwise, maintained by or with the consent of the exchange), and [4] any right of the exchange to the use of any property or service.

In 2015 the Commission noted that whether something is a ''facility'' is not always black and white, as ''any determination as to whether a service or other product is a facility of an exchange requires an analysis of the particular facts and circumstances.'' [16] Accordingly, the Exchange understands that the specific facts and circumstances of the Wireless Connections must be assessed before a determination can be made regarding whether or not they are facilities of the Exchange.[17]

The first prong of the definition is that ''facility,'' when used with respect to an exchange, includes ''its premises.'' That prong is not applicable in this case, because the Wireless Connections are not premises of the Exchange. The term ''premises'' is generally defined as referring to an entity's building, land, and appurtenances.[18] The wireless network that runs between IDS equipment in the Mahwah data center and IDS equipment in Third Party Data Centers, much of which is actually owned, operated and maintained by a non-ICE entity,[19] does not connect to the Exchange trading and execution systems and is not the premises of the Exchange. The portion of the Mahwah data center where the ''exchange'' functions are performed—*i.e.* the SRO Systems that bring together purchasers

[13] 15 U.S.C. 78c(a)(1).

[14] 17CFR 240.3b–16(a).

[15] 15 U.S.C. 78c(a)(2).

[16] Securities Exchange Act Release No. 76127 (October 9, 2015), 80 FR 62584 (October 16, 2015) (SR–NYSE–2015–36), at note 9 (order approving proposed rule change amending Section 907.00 of the Listed Company Manual). *See also* 79 FR 23389, *supra* note 7, at note 4 (noting that that the definition of the term ''facility'' has not changed since it was originally adopted) and 23389 (stating that the SEC ''has not separately interpreted the definition of 'facility'").

[17] As with the definition of ''exchange,'' the ICE Affiliates do not automatically fall within the definition of a ''facility.'' The definition focuses on ownership and the right to use properties and services, not corporate relationships. Indeed, if the term ''exchange'' in the definition of a facility included ''an exchange and its affiliates,'' then the rest of the functional prongs of the facility definition would be meaningless. Fundamental rules of statutory construction dictate that statutes be interpreted to give effect to each of their provisions, so as not to render sections of the statute superfluous.

[18] See, *e.g.,* definition of ''premises'' in Miriam-Webster Dictionary, at *https://www.merriam-webster.com/dictionary/premises,* and Cambridge English Dictionary, at *https://dictionary.cambridge.org/us/dictionary/english/premises.*

[19] A non-ICE entity owns, operates and maintains the wireless network between the Mahwah data center and the Carteret and Secaucus Third Party Data Centers pursuant to an agreement between the non-ICE entity and an ICE Affiliate.

and sellers of securities and perform with respect to securities the functions commonly performed by a stock exchange—could be construed as the ''premises'' of the Exchange, but the same is not true for a wireless network that is almost completely outside of the Mahwah data center.

The second prong of the definition of ''facility'' provides that a facility includes the exchange's ''tangible or intangible property whether on the premises or not.'' The Wireless Connections are not the property of the Exchange: They are services. The underlying wireless network is owned by ICE Affiliates and a non-ICE entity. As noted, the Act does not automatically collapse affiliates into the definition of an ''exchange.'' A review of the facts set forth above shows that there is a real distinction between the Exchange and its ICE Affiliates with respect to the Wireless Connections, and so something owned by an ICE Affiliate is not owned by the Exchange.

The third prong of the definition of ''facility'' provides that a facility includes

> any right to the use of such premises or property or any service thereof for the purpose of effecting or reporting a transaction on an exchange (including, among other things, any system of communication to or from the exchange, by ticker or otherwise, maintained by or with the consent of the exchange).[20]

This prong does not capture the Wireless Connections because the Exchange does not have the right to use the Wireless Connections to effect or report a transaction on the Exchange. ICE Affiliates and a non-ICE entity own and maintain the wireless network underlying the Wireless Connections, and ICE Affiliates, not the Exchange, offer and provide the Wireless Connections to customers. The Exchange does not know whether or when a market participant has entered into an agreement for a Wireless Connection and has no right to approve or disapprove of the provision of a Wireless Connection, in the same way that the Exchange would have no right to approve or disapprove of the provision of connectivity to a market participant in co-location or elsewhere by any other provider. The Exchange does not put content onto the Wireless Connections. When a customer terminates a Wireless Connection, the Exchange does not consent to the termination.

The Wireless Connections do not connect to the Exchange trading and execution systems. As such, the Wireless Connections are not provided for ''the purpose of effecting or reporting a transaction on'' the Exchange. Rather, a Wireless Connection facilitates the customer's interaction with itself. Each Wireless Connection connects the IDS equipment in the Third Party Data Center and IDS equipment in the Mahwah data center. At either end of the Wireless Connection, the customer uses a cross connect or other cable to connect its own equipment to the IDS equipment. In the Mahwah data center, the cross connect leads to the customer's server in co-location, not the Exchange trading and execution systems.

It is important to remember that the customers' equipment in the Mahwah data center is not provided by, part of, or a facility of, the Exchange. The Exchange provides the space in which customers' equipment is housed, and permits customers to use their equipment to communicate with the SRO Systems through services, such as connections to the local area networks, that are filed with the Commission.[21] The Exchange provides the space, but not the equipment. Accordingly, even if a customer were to use a Wireless Connection to send instructions to trade or to receive a report of a trade, the customer would not be sending instructions to the Exchange, but rather to its own equipment.

The Exchange believes the example in the parenthetical in the third prong of the definition of ''facility'' cannot be read as an independent prong of the definition. Such a reading would ignore that the parentheses and the word ''including'' clearly indicate that ''any system of communication to or from an exchange . . . maintained by or with the consent of the exchange'' is explaining the preceding text. By its terms, the parenthetical is providing a non-exclusive example of the type of property or service to which the prong refers, and does not remove the requirement that there must be a right to use the premises, property or service to effect or report a transaction on an exchange. It is making sure the reader understands that ''facility'' includes a ticker system that an exchange has the right to use, not creating a new fifth prong to the definition. In fact, if the ''right to use'' requirement were ignored, every communication provider that connected to an exchange, including any broker-dealer system and telecommunications network, would become a facility of that exchange so long as the exchange consented to the connection, whether or not the connection was used to trade or report a trade, and whether or not the exchange had any right at all to the use of the connection.

The fourth prong of the definition provides that a facility includes ''any right of the exchange to the use of any property or service.''[22] As described above, the Exchange does not have the right to use the Wireless Connections. Instead, the customers of the Wireless Connections are customers who enter into an agreement with ICE Affiliates for connections over a wireless network, much of which is owned, operated and maintained by a non-ICE entity.

Accordingly, for all the reasons discussed above, the Wireless Connections provided by ICE Affiliates are not facilities of the Exchange.

The legal conclusion that the Wireless Connections are not facilities of the Exchange is strongly supported by the facts. The Wireless Connections are neither necessary for, nor integrally connected to, the operations of the Exchange. They are empty pipes that customers can use as they like. In this context, IDS simply acts as a vendor selling connectivity, just like the other vendors that offer wireless connections in the Carteret and Secaucus Third Party Data Centers and fiber connections to all the Third Party Data Centers. The fact that in this case it is ICE Affiliates that offer the Wireless Connections does not make the Wireless Connections facilities of the Exchange any more than are the connections offered by other parties.

Further, the Exchange believes that requiring it to file this proposed rule change is not necessary in order for the Commission to ensure that the Exchange is satisfying its requirements under the Act. Because, as described above, the Wireless Connections are not necessary for, nor connected to, the operations of the Exchange, and customers are not required to use the Wireless Connections, holding the Wireless Connections to the statutory standards in Section 6(b) serves no purpose.

Instead, the sole impact of the requirement that the Exchange file the Wireless Connections is to place an

[20] 15 U.S.C. 78c(a)(2).

[21] *See* Securities Exchange Act Release No. 63275 (November 8, 2010), 75 FR 70048 (November 16, 2010) (SR–NYSEArca–2010–100) notice of filing and immediate effectiveness of proposed rule change amending the schedules of fees and charges for exchange services for both its equities and options platforms to reflect fees charged for co-location services). As described by the Commission, co-location is when a ''trading center . . . rents rack space to market participants that enables them to place their servers in close physical proximity to a trading center's matching engine.'' 75 FR 3594, *supra* note 7, at 3610 (noting that ''[c]o-location helps minimize network and other types of latencies between the matching engine of trading centers and the servers of market participants'').

[22] *Id.*

undue burden on competition on the ICE Affiliates that offer the connections, compared to their market competitors. This filing requirement, thus, itself is inconsistent with the requirement under Section 6(b)(8) of the Act that the rules of the exchange not ''impose any burden on competition not necessary or appropriate in furtherance of the purposes of [the Act].'' [23] This burden on competition arises because IDS would be unable, for example, to offer a client or potential client a different bandwidth it requests, without the delay and uncertainty of a filing, but its competitors will. Similarly, if a competitor decides to undercut IDS' fees because IDS, unlike the competitor, has to make its fees public, IDS will not be able to respond quickly, if at all. Indeed, because its competitors are not required to make their services or fees public, and are not subject to a Commission determination of whether such services or fees are ''not unfairly discriminatory'' or equitably allocated, IDS is at a competitive disadvantage from the very start.

The Proposed Service and Fees

As noted above, the Exchange proposes to add to its rules a Wireless Fee Schedule setting forth the fees charged by IDS related to the Wireless Connections between the Mahwah data center and the Third Party Data Centers.

For each Wireless Connection, a customer would be charged a non-recurring initial charge and a monthly recurring charge (''MRC'') that would vary depending upon bandwidth and the location of the connection. The proposal would waive the first month's MRC, to allow customers to test a new Wireless Connection for a month before incurring any MRCs, and the Exchange proposes to add text to the Wireless Fee Schedule accordingly. If a customer had an existing Wireless Connection and opted to upgrade or downgrade to a different size circuit connecting to the same Third Party Access Center, it would not be subject to the initial charge.

The Exchange proposes to establish the Wireless Fee Schedule with a section under the heading ''A. Wireless Connectivity'' setting forth the fees charged by IDS related to the Wireless Connections, as follows:

Type of service	Description	Amount of charge
Wireless Connection between Mahwah Data Center and Secaucus access center.	10 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $9,000.
Wireless Connection between Mahwah Data Center and Secaucus access center.	50 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $13,500.
Wireless Connection between Mahwah Data Center and Secaucus access center.	100 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $23,000.
Wireless Connection between Mahwah Data Center and Secaucus access center.	200 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $44,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	10 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $10,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	50 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $15,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	100 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $25,000.
Wireless Connection between Mahwah Data Center and Carteret access center.	200 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $45,000.
Wireless Connections between (a) Mahwah Data Center and Carteret access center and (b) Mahwah Data Center and Secaucus Data Center.	50 Mb Circuits	$15,000 initial charge for both connections plus monthly charge for both connections of $22,000.
Wireless Connection between Mahwah Data Center and Markham access center.	1 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $6,000.
Wireless Connection between Mahwah Data Center and Markham access center.	5 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $15,500.
Wireless Connection between Mahwah Data Center and Markham access center.	10 Mb Circuit	$10,000 per connection initial charge plus monthly charge per connection of $23,000.

Proposed General Note

The Exchange and each of the Affiliate SROs are filing the Wireless Connections. Although each such market will have a Wireless Fee Schedule, a market participant that obtains a Wireless Connection will not be charged more than once for that service, irrespective of whether it is a member of one, some or none of the Exchange and the Affiliate SROs. Accordingly, the Exchange proposes that the Wireless Fee Schedule include a General Note that describes the billing practice for market participants, as follows:

A market participant that incurs fees from the New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc. or NYSE National, Inc. (collectively, the ''Affiliate SROs'') for a particular service pursuant to this Fee Schedule shall not be subject to fees for the same service charged by the other Affiliate SROs.

The proposed General Note would be consistent with the first general note in the co-location section of the Exchange and Affiliate SROs' price lists and fee schedule,[24] as well as the Nasdaq Stock Market rules.[25]

Application and Impact of the Proposed Change

The proposed change would apply to all market participants equally. The proposed change would not apply differently to distinct types or sizes of market participants. Market participants that require other types or sizes of network connections between the Mahwah data center and the Third Party Data Centers could still request them. The purchase of the service is

[23] 15 U.S.C. 78f(b)(8).

[24] *See* Securities Exchange Act Release Nos. 70206 (August 15, 2013), 78 FR 51765 (August 21, 2013) (SR–NYSE–2013–59); 70176 (August 13, 2013), 78 FR 50471 (August 19, 2013) (SR–NYSEMKT–2013–67); 70173 (August 13, 2013), 78 FR 50459 (August 19, 2013) (SR–NYSEArca–2013–80); 83351 (May 31, 2018), 83 FR 26314 (June 6, 2018) (SR–NYSENAT–2018–07; and 87408 (October 28, 2019), 84 FR 58778 (November 1, 2019) (SR–NYSECHX–2019–12).

[25] *See, e.g.,* The Nasdaq Stock Market General Equity and Options Rules, General 8, Section 1.

completely voluntary and the Wireless Fee Schedule will be applied uniformly to all market participants.

Competitive Environment

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have additional options. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

Wireless connections involve beaming signals through the air between antennas that are within sight of one another. Because the signals travel a straight, unimpeded line, and because light waves travel faster through air than through glass (fiber optics), wireless messages have lower latency than messages travelling through fiber optics. At the same time, as a general rule wireless networks have less uptime than fiber networks. Wireless networks are directly and immediately affected by adverse weather conditions, which can cause message loss and outage periods. Wireless networks cannot be configured with redundancy in the same way that fiber networks can. As a result, an equipment or weather issue at any one location on the network will cause the entire network to have an outage. In addition, maintenance can take longer than it would with a fiber based network, as the relevant tower may be in a hard to reach location, or weather conditions may present safety issues, delaying technicians servicing equipment. Even under normal conditions, a wireless network will have a higher error rate than a fiber network of the same length.

The proposed Wireless Connections traverse wireless connections through a series of towers equipped with wireless equipment, including, in the case of the Carteret and Secaucus connections, a pole on the grounds of the Mahwah data center. With the exception of the non-ICE entity that owns the wireless network used for the Wireless Connections to Secaucus and Carteret,[26] third parties do not have access to such pole. However, access to such pole is not required for third parties to establish wireless networks that can compete with the Wireless Connections to the Carteret and Secaucus Third Party Data Centers, as witnessed by the existing wireless connections offered by non-ICE entities currently serving market participants.

Proximity to a data center is not the only determinant of a wireless network's latency. Rather, the latency of a wireless network depends on several factors. Variables include the wireless equipment utilized; the route of, and number of towers or buildings in, the network; and the fiber equipment used at either end of the connection. Moreover, latency is not the only consideration that a market participant may have in selecting a wireless network. Other considerations may include the bandwidth of the offered connection; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

2. Statutory Basis

Although the Exchange does not believe that the present proposed change is a change to the ''rules of an exchange'' [27] required to be filed with the Commission under the Act, the Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[28] in general, and furthers the objectives of Section 6(b)(5) of the Act,[29] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and does not unfairly discriminate between customers, issuers, brokers, or dealers. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[30] 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

The Exchange believes its proposal is reasonable.

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham.

The Wireless Connections provide market participants with one means of connectivity, but substitute products are available, as witnessed by the existing wireless connections offered by non-ICE entities currently serving market participants. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

Market participants' considerations in determining what connectivity to purchase may include latency; bandwidth size; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions.

[26] *See* note 19, *supra*.

[27] *See* 15 U.S.C. 78c(a)(27) (defining the term ''rules of an exchange'').

[28] 15 U.S.C. 78f(b).

[29] 15 U.S.C. 78f(b)(5).

[30] 15 U.S.C. 78f(b)(4).

Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange believes that the proposed pricing for the Wireless Connections is reasonable because it allows market participants to select the connectivity options that best suit their needs. A market participant that opts to connect with a Wireless Network would be able to select the route and bandwidth that better suit its needs, thereby helping it tailor its operations to the requirements of its business operations. The fees also reflect the benefit received by customers in terms of lower latency over the fiber optics options.

Only market participants that voluntarily select to receive Wireless Connections are charged for them, and those services are available to all market participants. Furthermore, the Exchange believes that the services and fees proposed herein are reasonable because, in addition to the services being completely voluntary, they are available to all market participants on an equal basis (*i.e.,* the same products and services are available to all market participants). All market participants that voluntarily select Wireless Connections would be charged the same amount for the same services and would have their first month's MRC for Wireless Connections waived.

Overall, the Exchange believes that the proposed change is reasonable because the Wireless Connections described herein are offered as a convenience to market participants, but offering them requires the provision, maintenance and operation of the Mahwah data center, wireless networks and access centers in the Third Party Data Centers, including the installation and monitoring, support and maintenance of the services.

The Exchange believes that the proposed waiver of the first month's MRC is reasonable as it would allow customers to test a Wireless Connection for a month before incurring any monthly recurring fees and may act as an incentive to market participants to connect to a Wireless Connection. The Exchange believes that the proposed waiver of the initial charge if a customer has an existing Wireless Connection and opted to upgrade or downgrade to a different size circuit at the same Third Party Data Center is reasonable because the change in Wireless Connection would not require IDS to do any physical work to implement the connection.

The Exchange believes that its proposed General Note is reasonable because it would provide transparency regarding how the billing practice for Wireless Connections functions. The Exchange believes that a customer should not be charged more than once for a Wireless Connection. For example, to charge one customer twice for a Wireless Connection because that customer is a member of two Affiliate SROs, and so subject to the rules of both Affiliate SROs, when another customer that buys the same Wireless Connection only pays once, would not promote just and equitable principles of trade, and could result in the Exchanges and Affiliate SROs receiving the proceeds from multiple fees despite only providing a service once.

The Proposed Change Is an Equitable Allocation of Fees and Credits

The Exchange believes its proposal equitably allocates its fees among its market participants.

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all market participants equally. As is currently the case, the purchase of any connectivity service is completely voluntary and the Wireless Fee Schedule will be applied uniformly to all customers.

Without this proposed rule change, market participants seeking connectivity to a Third Party Data Center would have fewer options. With it, because the Wireless Connections are offered at different bandwidths and price points, market participants have more choices with respect to the form and price of the connectivity they use, allowing a market participant that opts to connect with a wireless network to select the connectivity and bandwidth that better suit its needs, thereby helping it tailor its operations to the requirements of its business operations.

The Exchange believes that its proposed General Note is equitable because a customer would not be charged more than once for a Wireless Connection. For example, to charge one customer twice for a Wireless Connection because that customer is a member of two Affiliate SROs, and so subject to the rules of both Affiliate SROs, when another customer that buys the same Wireless Connection only pays once, would not promote just and equitable principles of trade, and could result in the Exchanges and Affiliate SROs receiving the proceeds from multiple fees despite only providing a service once. The Exchange believes that its proposed General Note is reasonable because it would provide transparency regarding how the billing practice for Wireless Connections functions.

The Proposed Change Is Not Unfairly Discriminatory

The Exchange believes its proposal is not unfairly discriminatory.

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all market participants equally. As is currently the case, the purchase of any connectivity service is completely voluntary and the Wireless Fee Schedule will be applied uniformly to all customers.

Without this proposed rule change, market participants seeking connectivity to a Third Party Data Center would have fewer options. With it, because the Wireless Connections are offered at different bandwidths and price points, market participants have more choices with respect to the form and price of the connectivity they use, allowing a market participant that opts to connect with a wireless network to select the connectivity and bandwidth that better suit its needs, thereby helping it tailor its operations to the requirements of its business operations.

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have additional options. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers.

Market participants' considerations in determining what connectivity to

purchase may include latency; bandwidth size; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange believes that its proposed General Note would not be unfairly discriminatory because a customer would not be charged more than once for a Wireless Connection. For example, to charge one customer twice for a Wireless Connection because that customer is a member of two Affiliate SROs, and so subject to the rules of both Affiliate SROs, when another customer that buys the same Wireless Connection only pays once, would not promote just and equitable principles of trade, and could result in the Exchanges and Affiliate SROs receiving the proceeds from multiple fees despite only providing a service once.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the only burden on competition of the proposed change is on IDS and other commercial connectivity providers. Solely because IDS is wholly owned by the same parent company as the Exchange, IDS will be at a competitive disadvantage to its commercial competitors, and its commercial competitors, without a filing requirement, will be at a relative competitive advantage to IDS.

By permitting IDS to continue to offer the Wireless Connectivity, approval of the proposed changes would contribute to competition by allowing IDS to compete with other connectivity providers, and thus provides market participants another connectivity option. For this reason, the proposed rule changes will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[31]

There are currently at least three other vendors that offer market participants wireless network connections between the Mahwah data center and the Secaucus and Carteret Third Party Access Centers using wireless equipment installed on towers and buildings near the Mahwah data center. In addition, some market participants have their own proprietary wireless networks. Based on the information available to it, the Exchange believes that the wireless connections offered by non-ICE entities provide connectivity at the same or similar speed as the Wireless Connections, and at the same or similar cost. The Exchange believes the Wireless Connections between the Mahwah data center and the Markham Third Party Data Center are the first public, commercially available wireless connections between the two points, creating a new connectivity option for customers in Markham. Importantly, the Exchange does not control the Third Party Data Centers and could not preclude other parties from creating new wireless or fiber connections to any of the Third Party Data Centers.

Market participants that want a connection between a Third Party Data Center and the Mahwah data center have additional options. A market participant may create a new proprietary wireless connection, connect through another market participant, or utilize fiber connections offered by the Exchange, ICE Affiliates, other service providers and third party telecommunications providers. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The proposed Wireless Connections traverse wireless connections through a series of towers equipped with wireless equipment, including, in the case of the Carteret and Secaucus connections, a pole on the grounds of the Mahwah data center. With the exception of the non-ICE entity that owns the wireless network used for the Wireless Connections to Secaucus and Carteret,[32] third parties do not have access to such pole, as the IDS wireless network has exclusive rights to operate wireless equipment on the Mahwah data center pole. IDS does not sell rights to third parties to operate wireless equipment on the pole, due to space limitations, security concerns, and the interference that would arise between equipment placed too closely together.

Access to the pole or roof is not required for other parties to establish wireless networks that can compete with the Wireless Connections, as witnessed by the existing wireless connections offered by non-ICE entities currently serving market participants. The latency of a wireless network depends on several factors, not just proximity to a data center. Variables include the wireless equipment utilized; the route of, and number of towers or buildings in, the network; and the fiber equipment used at either end of the connection. In addition, latency is not the only consideration that a market participant may have in selecting a wireless network. Market participants' considerations in determining what connectivity to purchase may include latency; bandwidth size; amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions.

The Exchange operates in a highly competitive market in which exchanges and other vendors offer connectivity options between data centers as a means to facilitate the trading and other market activities of market participants. 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 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.'' [33]

The proposed change does not affect competition among national securities exchanges or among members of the Exchange, but rather between IDS and its commercial competitors.

For the reasons described above, the Exchange believes that the proposed rule changes reflect this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or 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 the proposed rule change, or

[31] 15 U.S.C. 78f(b)(8).

[32] *See* note 19, *supra.*

[33] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, at 37499 (June 29, 2005).

(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–NYSEArca–2020–08 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–2020–08. 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–2020–08, and should be submitted on or before March 10, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–03097 Filed 2–14–20; 8:45 am]

BILLING CODE 8011–01–P

[34] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88163; File No. SR–NSCC–2020–002]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing of Proposed Rule Change to Enhance the Calculation of the Family-Issued Securities Charge

February 11, 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 January 28, 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.[3] 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 modifications to NSCC's Rules and Procedures (''Rules'')[4] in order to enhance the calculation of NSCC's existing charge applied to long positions in Family-Issued Securities[5] (''FIS Charge'') by using the same haircut percentages for all Members and no longer using Members' ratings on the Credit Risk Rating Matrix (''CRRM'')[6] in calculating this charge, as 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

NSCC is proposing to modify the Rules to enhance the calculation of the FIS Charge by using the same haircut percentages for all Members and no longer using Members' ratings on the CRRM in calculating this charge. By using the same haircut percentages to calculate the FIS Charge for all Members, NSCC believes this proposed enhancement would better mitigate the specific wrong-way risk posed by long positions in Family-Issued Securities that the charge was designed to address, as described below.

Background

As a central counterparty, NSCC occupies an important role in the securities settlement system by interposing itself between counterparties to financial transactions, thereby reducing the risk faced by participants and contributing to global financial stability. The effectiveness of a central counterparty's risk controls and the adequacy of its financial resources are critical to achieving these risk-reducing goals. As part of its market risk management strategy, NSCC manages its credit exposure to Members by determining the appropriate Required Fund Deposits to the Clearing Fund and monitoring its sufficiency, as provided for in the Rules.[7] The Required Fund Deposit serves as each Member's margin.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] On January 28, 2020, NSCC filed this proposed rule change as an advance notice (SR–NSCC–2020–801) with the Commission pursuant to 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, 12 U.S.C. 5465(e)(1), and Rule 19b–4(n)(1)(i) under the Act, 17 CFR 240.19b–4(n)(1)(i). A copy of the advance notice is *available at http://www.dtcc.com/legal/sec-rule-filings.aspx.*

[4] Terms not defined herein are defined in the Rules, *available at www.dtcc.com/~/media/Files/Downloads/legal/rules/nscc_rules.pdf.*

[5] A Family-Issued Security is defined in Rule 1 (Definitions and Descriptions) of the Rules as ''a security that was issued by a Member or an affiliate of that Member.'' *Supra* note 4.

[6] *See* Rule 1 and Section 4 of Rule 2B of the Rules, *supra* note 4. *See also* Securities Exchange Act Release Nos. 80734 (May 19, 2017), 82 FR 24177 (May 25, 2017) (SR–DTC–2017–002, SR–FICC–2017–006, SR–NSCC–2017–002); and 80731 (May 19, 2017), 82 FR 24174 (May 25, 2017) (SR–DTC–2017–801, SR–FICC–2017–804, SR–NSCC–2017–801).

[7] *See* Rule 4 (Clearing Fund) and Procedure XV (Clearing Fund Formula and Other Matters) of the Rules, *supra* note 4.

The objective of a Member's Required Fund Deposit is to mitigate potential losses to NSCC associated with liquidating a Member's portfolio in the event NSCC ceases to act for that Member (hereinafter referred to as a ''default'').[8] The aggregate of all Members' Required Fund Deposits constitutes the Clearing Fund of NSCC.[9] NSCC may access its Clearing Fund should a defaulting Member's own Required Fund Deposit be insufficient to satisfy losses to NSCC caused by the liquidation of that Member's portfolio.[10]

Pursuant to the Rules, each Member's Required Fund Deposit amount consists of a number of applicable components, each of which is calculated to address specific risks faced by NSCC, as identified within Procedure XV of the Rules.[11] NSCC regularly assesses the market, liquidity and other risks that its margining methodologies are designed to mitigate to evaluate whether margin levels are commensurate with the particular risk attributes of each relevant product, portfolio, and market.

Among the various risks that NSCC considers when evaluating the effectiveness of its margining methodology are its counterparty risks, including wrong-way risk. In particular, NSCC seeks to identify and mitigate its exposures to specific wrong-way risk, which is defined as the risk that an exposure to a counterparty is highly likely to increase when the creditworthiness of that counterparty deteriorates.[12] NSCC has identified exposure to specific wrong-way risk when it acts as central counterparty to a Member with long positions in Family-Issued Securities. In the event a Member with long positions in Family-Issued Securities defaults, NSCC would close out those positions following a likely drop in the creditworthiness of the issuer, possibly resulting in a loss to NSCC.

In order to address this exposure to specific wrong-way risk, NSCC implemented the FIS Charge in 2015.[13] The FIS Charge is applied to a Member's long positions in Family-Issued Securities, which are the positions NSCC would need to sell into the market following a Member default.[14]

When the FIS Charge was initially implemented, it was only applied to Members that were placed on the Watch List based on the CRRM rating.[15] As part of its ongoing monitoring of its membership, NSCC utilizes the internal CRRM to evaluate its credit risk exposures to its Members based on a scale from strongest to weakest.[16] Members that fall within the higher risk rating categories are considered on NSCC's Watch List and may be subject to enhanced surveillance or additional margin charges, as permitted under the Rules.[17] Therefore, the FIS Charge was applied only to Members on the Watch List based on the reasoning that these Members present a heightened credit risk to NSCC or have demonstrated higher risk related to their ability to meet settlement. However, in the Initial FIS Filing, NSCC proposed to further evaluate its exposure to wrong-way risk presented by positions in Family-Issued Securities by reviewing the impact of expanding the application of the FIS Charge to positions in Family-Issued Securities of all Members.[18]

Following that evaluation, NSCC implemented the current methodology for calculating the FIS Charge, which expanded the application of the charge to all Members, but continues to take into account Members' ratings on the CRRM in calculating the applicable charge.[19] Therefore, under the current methodology, in calculating its Members' Required Fund Deposits, NSCC first excludes long positions in Family-Issued Securities of Members from the applicable volatility charge, and instead charges an amount calculated by multiplying the absolute value of the long Net Unsettled Positions (as such term is defined in Procedure XV of the Rules) in that Member's Family-Issued Securities by a percentage that is no less than 40 percent.[20] The percentage that is used in calculating the FIS Charge depends on a Member's rating on the CRRM. Under Procedure XV of the Rules, long Net Unsettled Positions in (1) fixed income securities that are Family-Issued Securities are charged a haircut rate of no less than 80 percent for Members that are rated 6 or 7 on the CRRM, and no less than 40 percent for Members that are rated 1 through 5 on the CRRM; and (2) equity securities that are Family-Issued Securities are charged a haircut rate of 100 percent for Members that are rated 6 or 7 on the CRRM, and no less than 50 percent for Members that are rated 1 through 5 on the CRRM.[21] The haircut rates used in the FIS Charge as applied to positions in fixed income securities were calibrated based on historical corporate issue recovery rate data and address the risk that the Family-Issued Securities of a Member would be devalued in the event of that Member's default.

Proposed Change

NSCC is now proposing to enhance the methodology for calculating the FIS Charge by using the higher applicable percentage for all Members, and no longer using a Member's CRRM rating in the calculation.

Since implementation of the current calculation, NSCC has continued to monitor its exposure to specific wrong-way risk and determined that the risk characteristics to be considered when margining Family-Issued Securities extend beyond Members' creditworthiness as measured through the CRRM. More specifically, NSCC believes it may be exposed to specific wrong-way risk despite a Members' rating on the CRRM, and NSCC can better mitigate its exposure to this risk by calculating the FIS Charge without considering Members' CRRM ratings. While the current methodology appropriately assumes that Members with a higher rating on the CRRM present a heightened credit risk to NSCC or have demonstrated higher risk related to their ability to meet settlement, NSCC believes this approach does not take into account the risk that a firm may default due to unanticipated causes (referred to as a ''jump-to-default'' scenario) not captured by the CRRM rating. The CRRM rating necessarily relies on historical data as a predictor of future risks. Jump-to-default scenarios

[8] The Rules identify when NSCC may cease to act for a Member and the types of actions NSCC may take. For example, NSCC may suspend a firm's membership with NSCC or prohibit or limit a Member's access to NSCC's services in the event that Member defaults on a financial or other obligation to NSCC. *See* Rule 46 (Restrictions on Access to Services) of the Rules, *supra* note 4.

[9] *See* Rule 4 (Clearing Fund) of the Rules, *supra* note 4.

[10] *Id.*

[11] *Supra* note 4.

[12] *See* Principles for financial market infrastructures, issued by the Committee on Payment and Settlement Systems and the Technical Committee of the International Organization of Securities Commissions, pg. 47 n.65 (April 2012), *available at http://www.bis.org/publ/cpss101a.pdf.*

[13] *See* Securities Exchange Act Release No. 76077 (October 5, 2015), 80 FR 61256 (October 9, 2015) (SR–NSCC–2015–003) (''Initial FIS Filing'').

[14] Short positions in Family-Issued Securities are not subject to the FIS Charge and are subject to the applicable volatility charge, as provided for under the Rules. *See* Sections I.(A)(1)(a)(iv) and I.(A)(2)(a)(iv) of Procedure XV (Clearing Fund Formula and Other Matters) of the Rules, *supra* note 4.

[15] *See supra* note 13.

[16] *See supra* note 6.

[17] *Id.*

[18] *Supra* note 13, at 61257.

[19] *See* Securities Exchange Act Release Nos. 81550 (September 7, 2017), 82 FR 43061 (September 13, 2017) (SR–NSCC–2017–010); and 81545 (September 7, 2017), 82 FR 43054 (September 13, 2017) (SR–NSCC–2017–804).

[20] *See* Sections I.(A)(1)(a)(iv) and I.(A)(2)(a)(iv) of Procedure XV (Clearing Fund Formula and Other Matters) of the Rules, *supra* note 4.

[21] *Id.*

are triggered by unanticipated causes that could not be predicted based on historical trends or data, for example fraud or other bad acts by management. The proposed change is designed to improve NSCC's ability to cover the specific wrong-way risk posed by long positions in Family-Issued Securities by applying the higher applicable percentage in calculating the FIS Charge for all Members.

In order to implement this proposal, NSCC would amend Sections I.(A)(1)(a)(iv) and I.(A)(2)(a)(iv) of Procedure XV of the Rules, which describe the methodology for calculating the FIS Charge, and provide that (1) fixed income securities that are Family-Issued Securities shall be charged a haircut rate of no less than 80 percent; and (2) equity securities that are Family-Issued Securities shall be charged a haircut rate of 100 percent.

2. Statutory Basis

NSCC believes that the proposed change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a covered clearing agency. In particular, NSCC believes that the proposed change is consistent with Section 17A(b)(3)(F) of the Act,[22] and Rules 17Ad–22(e)(4)(i),[23] and (e)(6)(i) and (v),[24] each promulgated under the Act, for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions and to protect investors and the public interest.[25] The proposed change would enhance the margin methodology applied to long positions in Family-Issued Securities by using the higher applicable percentage for all Members, rather than considering Members' CRRM ratings in the calculation. The proposal would improve NSCC's ability to mitigate specific wrong-way risk exposures in a jump-to-default scenario and, in this way, would assist NSCC in collecting margin that more accurately reflects NSCC's exposure to a Member that clears Family-Issued Securities. The proposal would also assist NSCC in its continuous efforts to improve the reliability and effectiveness of its risk-based margining methodology by taking into account specific wrong-way risk. As such, the proposal would help NSCC, as a central counterparty, promote robust risk management, and thus promote the prompt and accurate clearance and settlement of securities transactions, as well as, in general, protect investors and the public interest, consistent with the requirements of Section 17A(b)(3)(F) of the Act.[26]

Rule 17Ad–22(e)(4)(i) under the Act requires that each covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by maintaining sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence.[27] The specific wrong-way risk presented by Family-Issued Securities is the risk that, in the event a Member with unsettled long positions in Family-Issued Securities defaults, NSCC would close out those positions following a likely drop in the credit-worthiness of the issuer, possibly resulting in a loss to NSCC. The haircut rates used in calculating the FIS Charge as applied to positions in fixed income securities were calibrated based on historical corporate issue recovery rate data, and, therefore, address the risk that the Family-Issued Securities of a Member would be devalued in the event of that Member's default. The proposal to apply the higher haircuts to all Members would assist NSCC in addressing specific wrong-way risk exposures in a jump-to-default scenario. By addressing this additional risk exposure, NSCC believes the proposal would allow it to calculate the FIS Charge in a way that more accurately reflects the risk characteristics of Family-Issued Securities. The proposal would, therefore, permit NSCC to more accurately identify, measure, monitor and manage its credit exposures to Members with long positions in Family-Issued Securities, and would assist NSCC in collecting and maintaining financial resources that reflect its credit exposures to those Members. Therefore, NSCC believes the proposed change is consistent with Rule 17Ad–22(e)(4)(i).[28]

Rule 17Ad–22(e)(6)(i) under the Act requires that each covered clearing agency that provides central counterparty services establish, implement, maintain and enforce written policies and procedures reasonably designed to cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market.[29] Rule 17Ad–22(e)(6)(v) under the Act requires that each covered clearing agency that provides central counterparty services establish, implement, maintain and enforce written policies and procedures reasonably designed to cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, uses an appropriate method for measuring credit exposure that accounts for relevant product risk factors and portfolio effects across products.[30]

As stated above, long positions in Family-Issued Securities present NSCC with exposure to specific wrong-way risk that, in the event a Member with these positions defaults, NSCC would close out those positions following a likely drop in the credit-worthiness of the issuer, possibly resulting in a loss to NSCC. The haircut rates used in the current methodology would continue to be used in the proposed methodology and as applied to positions in fixed income securities were calibrated based on historical corporate issue recovery rate data and address the risk that the Family-Issued Securities of a Member would be devalued in the event of that Member's default. Therefore, the calculation of the charge would continue to reflect the risk characteristics of Family-Issued Securities. As described above, the proposed change to apply the higher haircut rates to all Members would improve NSCC's ability to mitigate its exposure to specific wrong-way risk in a jump-to-default scenario. In this way, the proposal would assist NSCC in maintaining a risk-based margin system that considers, and produces margin levels commensurate with, the risks and particular attributes of long positions in Family-Issued Securities. Additionally, NSCC believes the proposed enhancement to the methodology for calculating the FIS Charge is an appropriate method for measuring its credit exposures to its Members, because the FIS Charge would continue to account for the risk factors presented by these securities, *i.e.,* the risk that these securities would be devalued in the event of a Member default. Therefore, NSCC believes the proposed change is consistent with Rule 17Ad–22(e)(6)(i) and (v).[31]

[22] 15 U.S.C. 78q–1(b)(3)(F).

[23] 17 CFR 240.17Ad–22(e)(4)(i).

[24] 17 CFR 240.17Ad–22(e)(6)(i) and (v).

[25] 15 U.S.C. 78q–1(b)(3)(F).

[26] *Id.*

[27] 17 CFR 240.17Ad–22(e)(4)(i).

[28] *Id.*

[29] 17 CFR 240.17Ad–22(e)(6)(i).

[30] 17 CFR 240.17Ad–22(e)(6)(v).

[31] 17 CFR 240.17Ad–22(e)(6)(i) and (v).

(B) Clearing Agency's Statement on Burden on Competition

By enhancing the methodology for calculating the FIS Charge, and, therefore, increasing the amount of margin that Members may be charged under the Rules, the proposed change may impose a burden on competition. More specifically, those Members that are currently rated 1–5 on the CRRM would be subject to an increased FIS Charge relative to the current applicable FIS Charge. However, Members' ratings on the CRRM are re-evaluated periodically and change from time to time. Therefore, all Members could have become subject to the higher FIS Charge at any time under the current methodology if their CRRM rating was increased to a 6 or 7 following a periodic reevaluation of their rating. Similarly, the volume of Net Unsettled Positions in Family-Issued Securities in a Member's portfolio could change periodically. The proposed enhancement to the calculation of the FIS Charge would be imposed on all Members on an individualized basis, based on the positions in their cleared portfolio, in an amount reasonably calculated to mitigate the risks posed to NSCC by those positions. Therefore, Members that present similar Net Unsettled Positions would have similar impacts on their Required Fund Deposits, and, as such, NSCC does not believe any burden on competition imposed by the proposed change would be significant.

Further, NSCC believes that any burden on competition imposed by the proposed change would be both necessary and appropriate in furtherance of NSCC's efforts to mitigate its risk exposures and meet the requirements of the Act,[32] as described in this filing and further below.

NSCC believes that the above described burden on competition that may be created by the proposed changes would be necessary in furtherance of the purposes of the Act, specifically Section 17A(b)(3)(F) of the Act,[33] because, as described above, the Rules must be designed to promote the prompt and accurate clearance and settlement of securities transactions and to protect investors and the public interest.

NSCC also believes the proposed change would be necessary in order to support NSCC's compliance with Rules 17Ad–22(e)(4)(i), and (e)(6)(i) and (v),[34] each promulgated under the Act, which require NSCC to establish, implement, maintain and enforce written policies and procedures reasonably designed to (x) effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by maintaining sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence; (y) cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market; and (z) cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, uses an appropriate method for measuring credit exposure that accounts for relevant product risk factors and portfolio effects across products. As described above, NSCC believes implementing the proposed enhancements to the FIS Charge would improve the risk-based methodology that NSCC employs to measure market price risk and would better limit NSCC's credit exposures to Members, consistent with these requirements.

NSCC believes that the above described burden on competition that could be created by the proposed changes would be appropriate in furtherance of the purposes of the Act, because such changes have been designed to promote the prompt and accurate clearance and settlement of securities transactions and to protect investors and the public interest, as described in detail above.

The proposed rule change would use the higher applicable haircut percentage in calculating the FIS Charge for all Members. These haircut percentages as applied to positions in fixed income securities were calibrated to address the risk that the Family-Issued Securities of a Member would be devalued in the event of that Member's default. Therefore, the proposed FIS Charge would better address NSCC's exposures to specific wrong-way risk with respect to all Members' positions in Family-Issued Securities, particularly in jump-to-default scenarios. By mitigating specific wrong-way risk for NSCC, the proposed change would also mitigate risk for Members, because lowering the risk profile for NSCC would in turn lower the risk exposure that Members may have with respect to NSCC in its role as a central counterparty. Further, NSCC believes that any burden on competition that may be imposed by this proposal would be appropriate in furtherance of the purposes of the Act, because it is designed to meet NSCC's risk management goals and its regulatory obligations.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

NSCC has not received or solicited any written comments relating to this proposal. NSCC will notify the Commission of any written comments received by NSCC.

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.

The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.

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–2020–002 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–NSCC–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

[32] 15 U.S.C. 78q–1(b)(3)(I).

[33] 15 U.S.C. 78q–1(b)(3)(F).

[34] 17 CFR 240.17Ad–22(e)(4) and (e)(6).

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–2020–002 and should be submitted on or before March 10, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[35]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–03092 Filed 2–14–20; 8:45 am]

BILLING CODE 8011–01–P

[35] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88161; File No. SR–BOX–2020–03]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule on the BOX Options Market LLC Facility To Establish BOX Connectivity Fees for Participants and Non-Participants Who Connect to the BOX Network

February 11, 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 January 29, 2020, BOX Exchange LLC (the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A)(ii) of the Act,[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon filing with the Commission. 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)(ii).

[4] 17 CFR 240.19b–4(f)(2).

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend the Fee Schedule regarding connectivity to BOX in order to provide greater detail and clarity concerning BOX's costs, as they pertain to expenses for network connectivity services, on the BOX Options Market LLC (''BOX'') options facility. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's internet website at *http://boxexchange.com.*

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 is refiling its proposal to amend the Fee Schedule regarding connectivity to BOX in order to provide greater detail and clarity concerning BOX's costs, as they pertain to expenses for network connectivity services. The Exchange is now presenting more connectivity cost details that correspond with income statement expense line items to provide greater transparency into its actual costs associated with providing network connectivity services. The Exchange believes that its proposed fees are fair and reasonable because they will permit recovery of less than all of the Exchange's costs for providing connectivity and will not result in excessive pricing or supracompetitive profit, when comparing the Exchange's total annual expense associated with providing the network connectivity services versus the total projected annual revenue the Exchange projects to collect for providing the network connectivity services.

The Exchange proposes to amend Section VI. (Technology Fees) of the BOX Fee Schedule to establish BOX Connectivity Fees for Participants and non-Participants who connect to the BOX network. Connectivity fees will be based upon the amount of bandwidth that will be used by the Participant or non-Participant. Further, BOX Participants or non-Participants connected as of the last trading day of each calendar month will be charged the applicable Connectivity Fee for that month. The Connectivity Fees will be as follows:

Connection type	Monthly fees (per connection)
Non-10 Gb Connection ...	$1,000
10 Gb Connection	5,000

The Exchange also proposes to amend certain language and numbering in Section VI.A to reflect the changes discussed above. Specifically, the Exchange proposes to add the title ''Third Party Connectivity Fees'' under Section VI.A. Further, the Exchange proposes to add Section VI.A.2, which details the proposed BOX Connectivity Fees discussed above. Finally the Exchange is proposing to remove Section VI.C. High Speed Vendor Feed (''HSVF''), and reclassify the HSVF as a Port Fee.

The Exchange initially filed the proposed fees on July 19, 2018, designating the proposed fees effective July 1, 2018. The first proposed rule change was published for comment in the **Federal Register** on August 2, 2018.[5] The Commission received one comment letter on the proposal.[6] The proposed fees remained in effect until they were temporarily suspended pursuant to a suspension order (the ''Suspension Order'') issued by the Division of Trading and Markets, which also instituted proceedings to determine whether to approve or disapprove the

[5] *See* Securities Exchange Act Release No. 83728 (July 27, 2018), 83 FR 37853 (August 2, 2018) (SR–BOX–2018–24).

[6] *See* Letter from Tyler Gellasch, Executive Director, The Healthy Markets Association, to Brent J. Fields, Secretary, Commission, dated August 23, 2018 (''Healthy Markets Letter'').

proposed rule change.[7] The Commission subsequently received one further comment letter on the proposed rule change, supporting the decision to suspend and institute proceedings on the proposed fee change.[8]

In response to the Suspension Order, the Exchange timely filed a Notice of Intention to Petition for Review [9] and Petition for Review to vacate the Division's Order,[10] which stayed the Division's suspension of the filing. On November 16, 2018 the Commission granted the Exchange's Petition for Review but discontinued the automatic stay.[11] The Exchange then filed a statement to reiterate the arguments set for in its petition for review and to supplement that petition with additional information.[12]

The Exchange subsequently refiled its fee proposal on November 30th, 2018. The proposed fees were noticed and again temporarily suspended pursuant to a suspension order issued by the Division of Trading and Markets, which also instituted proceedings to determine whether to approve or disapprove the proposed rule change.[13] The Commission received two comment letters supporting the decision to suspend and institute proceedings on the proposed fee change.[14]

The Exchange again refiled its fee proposal on February 13, 2019. The proposed fees were noticed and again temporarily suspended pursuant to a suspension order issued by the Division of Trading and Markets, which also instituted proceedings to determine whether to approve or disapprove the proposed rule change.[15] The Commission received four comment letters supporting the decision to suspend and institute proceedings on the proposed fee change.[16]

On March 29, 2019, the Commission issued its Order Disapproving each iteration of the BOX Proposal (''BOX Order''). In the BOX Order, the Commission highlighted a number of deficiencies it found in three separate rule filings by BOX to establish BOX's connectivity fees that prevented the Commission from finding that BOX's proposed connectivity fees were consistent with the Act.

On May 21, 2019 the Division of Trading and Markets released new Guidance on SRO Rule Filings Relating to Fees. The Exchange then refiled the proposed fees on June 26, 2019 to incorporate the new guidance released by the Commission.

The Commission received two comment letters on BOX's June 26, 2019 Proposal.[17] The Third SIFMA Comment Letter did not request that the Commission suspend BOX's Proposal, but rather requested that the Commission ''carefully consider whether BOX provided sufficient evidence to satisfy the applicable statutory standards.'' The Fourth Healthy Markets Letter walks through the procedural history of the BOX and MIAX filings and urges the Commission to propose reforms with regard to immediately effective rule filings.

On September 5, 2019 the Exchange withdrew the proposed rule change and refiled the proposed fees to further bolster its cost-based discussion to support its claim that the Proposal is fair and reasonable because they will permit recovery of a portion of BOX costs and will not result in excessive pricing or supra-competitive profit. The Commission received only one comment letter on the proposed rule change, twelve days after the comment period ended.[18] Of note, no Participant, other person, industry group, or operator of an options market commented on the proposed rule change. Rather, the only comment letter came from an operator of a single equities market (equities market structure and the resulting network demands are fundamentally different from those in the options markets) and which the operator also has a fundamentally different business model (and agenda) than does the Exchange. That letter called for, among other things, the Exchange to explain its basis for concluding it incurred substantially higher costs to provide lower-latency connections and further described the nature and closeness of the relationship between the identified costs and connectivity products and services as stated in the Exchange's cost allocation analysis.

The Exchange is again re-filing the fee proposal (''the Proposal'') to provide greater detail and clarity concerning the Exchange's costs, as they pertain to the Exchange's expense relating to the provision of network connectivity services. The Exchange is also refiling its proposal in order to clarify certain points raised in the IEX Letter.

The Exchange believes that the proposed fees are consistent with the Act because they (i) are reasonable, equitably allocated, not unfairly discriminatory, and not an undue burden on competition; (ii) comply with the BOX Order and the Guidance; (iii) are, as demonstrated by this Proposal and supported by evidence (including data and analysis), constrained by significant competitive forces; and (iv) are, supported by specific information (including quantitative information), fair and reasonable because they will permit recovery of a portion of BOX's costs and will not result in excessive pricing or supracompetitive profit. Accordingly, the Exchange believes that

[7] *See* Securities Exchange Act Release No. 34–84168 (September 17, 2018).

[8] *See* Letter from Theodore R. Lazo, Managing Director and Associate General Counsel, and Ellen Greene, Managing Director, Financial Services Operations, Securities Industry and Financial Markets Association, dated October 15, 2018.

[9] *See* Letter from Amir Tayrani, Partner, Gibson, Dunn & Crutcher LLP, dated September 19, 2018.

[10] *See* Petition for Review of Order Temporarily Suspending BOX Exchange LLC's Proposal to Amend the Fee Schedule on BOX Market LLC, dated September 26, 2018.

[11] *See* Securities Exchange Act Release No. 84614. Order Granting Petition for Review and Scheduling Filing of Statements, dated November 16, 2018. Separately, the Securities Industry and Financial Markets Association filed an application under Section 19(d) of the Exchange Act challenging the Exchange's proposed fees as alleged prohibitions or limitations on access. *See In re Securities Industry and Financial Markets Association,* Admin. Proc. File No. 3–18680 (Aug. 24, 2018). The Commission thereafter remanded that denial-of-access proceeding to the Exchange while ''express[ing] no view regarding the merits'' and emphasizing that it was ''not set[ting] aside the challenged rule change[ ].'' *In re Applications of SIFMA & Bloomberg,* Exchange Act Rel. No. 84433, at 2 (Oct. 16, 2018) (''Remand Order''), *available at https://www.sec.gov/litigation/opinions/2018/34-84433.pdf.* The Division's Suspension Order is inconsistent with the Commission's intent in the Remand Order to leave the challenged fees in place during the pendency of the remand proceedings and singles out the Exchange for disparate treatment because it means that the Exchange—unlike every other exchange whose rule changes were the subject of the Remand Order—is not permitted to continue charging the challenged fees during the remand proceedings.

[12] *See* Letter from Amir Tayrani, Partner, Gibson, Dunn & Crutcher LLP, dated December 10, 2018.

[13] *See* Securities Exchange Act Release No. 84823 (December 14, 2018), 83 FR 65381 (December 20, 2018) (SR–BOX–2018–37).

[14] *See* Letters from Tyler Gellasch, Executive Director, The Healthy Markets Association (''Second Healthy Markets Letter''), and Chester Spatt, Pamela R. and Kenneth B. Dunn Professor of Finance, Tepper School of Business, Carnegie Mellon University (''Chester Spatt Letter''), to Brent J. Fields, Secretary, Commission, dated January 2, 2019.

[15] *See* Securities Exchange Act Release No. 85201 (February 26, 2019), 84 FR 7146 (March 1, 2019)(SR–BOX–2019–04).

[16] *See* Letters from Theodore R. Lazo, Managing Director and Associate General Counsel, SIFMA (''Second SIFMA Comment Letter''), Tyler Gellasch, Executive Director, Healthy Markets Association (''Third Healthy Markets Letter''), Stefano Durdic, Former Owner of R2G Services, LLC, and Anand Prakash.

[17] *See* Letter from Theodore R. Lazo, Managing Director and Associate General Counsel, SIFMA, dated August 5, 2019 (''Third SIFMA Comment Letter'') and Letter from Tyler Gellasch, Executive Director, Healthy Markets Association, dated August 5, 2019 (''Fourth Healthy Markets Letter'').

[18] *See* Letter from John Ramsay, Chief Market Policy Officer, Investors Exchange LLC (''IEX'') to Vanessa Countryman, Secretary, Commission, dated October 9, 2019.

the Commission should find that the proposed fees are consistent with the Act. The proposed rule change is immediately effective upon filing with the Commission pursuant to Section 19(b)(3)(A) of the Act.

As discussed herein, the Exchange believes that it is reasonable and appropriate to begin charging for physical connectivity fees to partially offset the costs associated with maintaining and enhancing a state-of-the-art exchange network infrastructure in the U.S. options industry. There are significant costs associated with various projects and initiatives to improve overall network performance and stability, as well as costs paid to the third-party data centers for space rental, power used, etc.

BOX has always offered physical connectivity to Participants and non-Participants to access the BOX's trading platforms, market data, test systems and disaster recovery facilities. These physical connections consist of 10 Gb and non-10 Gb connections, where the 10 Gb connection provides for faster processing of messages sent to it in comparison to the non-10 Gb connection. Since launching in 2012, BOX has not charged for physical connectivity and has instead relied on transaction fees as the basis of revenue. However, in recent years transaction fees have continually decreased across the options industry. At the same time these transactions fees were decreasing, the options exchanges, except for BOX, began charging physical connectivity fees to market participants. As such, BOX began to find itself at a significant competitive disadvantage due to the decreased transaction fees at other exchanges. To remain competitive, BOX was forced to follow suit and decrease its transaction fees in order to continue receiving order flow to the Exchange. While other exchanges lowered transaction fees, they were still able to rely on the connectivity fee revenues as a means of covering a portion of the costs to operate their respective exchanges. BOX had no choice but to begin charging Participants and non-Participants fees for connecting directly to the BOX network (which BOX has taken considerable measures to maintain and enhance for the benefit of those Participants and non-Participants) in order to remain competitive with the other options exchanges in the industry.

As discussed in the Exchange's recent Petition for Review of the Commission's Order Disapproving BOX's three filings, not allowing BOX to charge such connectivity fees arbitrarily and inequitably treats BOX differently from each of the other exchanges that submitted prior immediately effective connectivity fee filings that were not suspended or disapproved by the Commission.[19] The Exchange notes that all other options exchanges currently charge for similar physical connectivity.[20]

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act, in general, and Section 6(b)(4) and 6(b)(5)of the Act,[21] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among BOX Participants and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [22]

The Exchange believes that the proposed fees in general constitute an equitable allocation of fees, and are not unfairly discriminatory, because they allow BOX to recover costs associated with offering access through the network connections. The proposed fees are also expected to offset the costs both the Exchange and BOX incur in maintaining and implementing ongoing improvements to the trading systems, including connectivity costs, costs incurred on software and hardware enhancements and resources dedicated to software development, quality assurance, and technology support.

The Exchange believes that its proposal is consistent with Section 6(b)(4) of the Act, in that the proposed fee changes are fair, equitable and not unreasonably discriminatory, because the fees for the connectivity alternatives available on BOX, as proposed, are constrained by significant competitive forces. The U.S. options markets are highly competitive (there are currently 16 options markets) and a reliance on competitive markets is an appropriate means to ensure equitable and reasonable prices. As stated above, BOX instituted the proposed fees after finding itself at a competitive disadvantage with other options exchanges. As other options exchanges lowered their transaction fees, they were still able to rely on the connectivity fee revenues as a means of covering a portion of the costs to operate their respective exchanges. By not charging for connectivity, BOX could not realistically compete for order flow through reduced transaction fees and still remain solvent.

Further, as the Exchange explained to the Division in previous filings and comment letters, the existence of robust competition between exchanges to attract order flow requires exchanges to keep prices for all of their joint services—including connectivity to the exchanges' networks at a pro-competitive level.[23] This conclusion is substantiated by the report prepared by Professor Janusz A. Ordover and Gustavo Bamberger addressing the theory of ''Platform Competition'' and its application to the pricing of exchanges' services, including connectivity services.[24] In the report, Ordover and Bamberger explain that ''the provision of connectivity services . . . is inextricably linked to the provision of trading services, so that, as

[19] *See* Securities Exchange Act Release No. 85927. Order Granting Petition for Review and Scheduling Filing of Statements, dated May 23, 2019.

[20] Nasdaq PHLX LLC (''Phlx''), The Nasdaq Stock Market LLC (''Nasdaq''), NYSE Arca, Inc. (''Arca''), NYSE American LLC (''NYSE American''), Nasdaq ISE, LLC (''ISE''), Cboe Exchange, Inc. (''Cboe''), Cboe BZX Exchange, Inc. (''CboeBZX''), Cboe EDGX Exchange, Inc. (''CboeEDGX'') and Cboe C2 Exchange, Inc. (''C2'') all offer a type of 10 Gb and non-10 Gb connectivity alternative to their participants. See Phlx, and ISE Rules, General Equity and Options Rules, General 8, Section 1(b). Phlx and ISE each charge a monthly fee of $2,500 for each 1 Gb connection, $10,000 for each 10 Gb connection and $15,000 for each 10 Gb Ultra connection, which is the equivalent of the Exchange's 10 Gb ULL connection. See also Nasdaq Price List—Trading Connectivity. Nasdaq charges a monthly fee of $7,500 for each 10 Gb direct connection to Nasdaq and $2,500 for each direct connection that supports up to 1 Gb. See also NYSE American Fee Schedule, Section V.B, and Arca Fees and Charges, Co-Location Fees. NYSE American and Arca each charge a monthly fee of $5,000 for each 1 Gb circuit, $14,000 for each 10 Gb circuit and $22,000 for each 10 Gb LX circuit, which is the equivalent of the Exchange's 10 Gb ULL connection. See also Cboe, CboeBZX, CboeEDGX and C2 Fee Schedules. Cboe charges monthly quoting and order entry bandwidth packet fees. Specifically, Cboe charges $1,600 for the 1st through 5th packet, $800 for the 6th through 8th packet, $400 for the 9th through 13th packet and $200 for the 14th packet and each additional packet. CboeBZX, CboeEDGX and C2 each charge a monthly fee of $2,500 for each 1 Gb connection and $7,500 for each 10 Gb connection.

[21] 15 U.S.C. 78f(b)(4) and (5).

[22] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

[23] Letter from Lisa J. Fall, BOX, to Brent J. Fields, Secretary, Securities and Exchange Commission (Feb. 19, 2019), *https://www.sec.gov/comments/sr-box-2018-24/srbox201824-4945872-178516.pdf.*

[24] *Id.*

a matter of economics, it is not possible to appropriately evaluate the pricing of connectivity services in isolation from the pricing of trading and other 'joint' services offered by'' an exchange. Ordover and Bamberger state that ''connectivity services are an 'input' into trading'' and that ''excessive pricing of such services would raise the costs of trading on [an exchange] relative to its rivals and thus discourage trading on'' that exchange.

Although the Ordover/Bamberger Statement focuses on the pricing of connectivity services by Nasdaq-affiliated equities exchanges, its ''overarching conclusion . . . that the pricing of connectivity services should not be analyzed in isolation'' applies with equal force to the proposed BOX fees. As discussed herein, BOX is engaged with rigorous competition with other exchanges to attract order flow to its platform. As such, BOX is constrained in its ability to price its joint services—including connectivity services—at supracompetitive levels. That competition ensures that BOX's connectivity fees are set at levels consistent with the requirements of the Exchange Act.

The Exchange acknowledges that there is no regulatory requirement that any market participant must connect to BOX, or that any participant must connect at any specific connection speed. The rule structure for options exchanges are, in fact, fundamentally different from those of equities exchanges. In particular, options market participants are not forced to connect to (and purchase market data from) all options exchanges, as shown by the number of Participants of BOX as compared to the much greater number of participants at other options exchanges. Not only does BOX have less than half the number of participants as certain other options exchanges, but there are also a number of BOX Participants that do not connect directly to BOX. Further, of the number of Participants that connect directly to BOX, many such Participants do not purchase market data from BOX. In addition, of the market makers that are connected to BOX, it is the individual needs of the market maker that require whether they need one connection or multiple connections to BOX. BOX has market maker Participants that only purchase one connection (10 Gb) and BOX has market maker Participants that purchase multiple connections. It is all driven by the business needs of the market maker. Market makers that are consolidators that target resting order flow tend to purchase more connectivity than market makers that simply quote all symbols on BOX. Even though non-Participants purchase and resell 10 Gb and non-10 Gb connections to both Participants and non-Participants, no market makers currently connect to BOX indirectly through such resellers.

The argument that all broker-dealers are required to connect to all exchanges is not true in the options markets. The options markets have evolved differently than the equities markets both in terms of market structure and functionality. For example, there are many order types that are available in the equities markets that are not utilized in the options markets, which relate to mid-point pricing and pegged pricing which require connection to the SIPs and each of the equities exchanges in order to properly execute those orders in compliance with best execution obligations. In addition, in the options markets there is a single SIP (OPRA) versus two SIPs in the equities markets, resulting in few hops and thus alleviating the need to connect directly to all the options exchanges. Additionally, in the options markets, the linkage routing and trade through protection are handled by the exchanges, not by the individual participants. Thus not connecting to an options exchange or disconnecting from an options exchange does not potentially subject a broker-dealer to violate order protection requirements as suggested by SIFMA. The Exchange recognizes that the decision of whether to connect to BOX is separate and distinct from the decision of whether and how to trade on BOX. The Exchange acknowledges that many firms may choose to connect to BOX, but ultimately not trade on it, based on their particular business needs.

Further, there is competition for connectivity to BOX. BOX competes with eleven (11) non-Participants who resell BOX connectivity or market data. These are resellers of BOX connectivity—they are not arrangements between broker dealers to share connectivity costs. Those non-Participants resell that connectivity to multiple market participants over that same connection, including both Participants and non-Participants of BOX. When connectivity is re-sold by a third-party, BOX does not receive any connectivity revenue from that sale. It is entirely between the third-party and the purchaser, thus constraining the ability of BOX to set its connectivity pricing as indirect connectivity is a substitute for direct connectivity. There are currently eleven (11) non-Participants that purchase connectivity to BOX. Those non-Participants resell that connectivity or market data to approximately twenty-seven (27) customers, some of whom are agency broker-dealers that have tens of customers of their own. Some of those twenty-seven (27) customers also purchase connectivity directly from BOX. Accordingly, indirect connectivity is a viable alternative that is already being used by non-Participants of BOX, constraining the price that BOX is able to charge for connectivity.

Prior to charging the proposed connectivity fees to market participants, the Exchange distributed an Informational Circular to all subscribers detailing the fees.[25] The circular stated that Participants connected as of the last trading day of each calendar month would be charged the applicable connectivity fee for that month. In addition to the Circular, the Exchange reached out to certain non-Participants[26] connected to BOX to ensure they knew of the upcoming connectivity fees and allow them the opportunity to disconnect any old connections before being charged. Finally, the Exchange instituted a grace period where Participants could contact the Exchange and make modifications to their connections (*i.e.* disconnect, add, downsize, etc.) prior to being charged the new connectivity fees. This grace period was in effect until August 7, 2018.

The Exchange is comprised of 51 BOX Participants. Of those 51 Participants, 24 Participants have purchased 10 Gb or non-10 Gb connections or some combination of multiple various connections.[27] The remaining Participants who have not purchased any connectivity to BOX are still able to trade on BOX indirectly through other Participants or non-Participant service bureaus that are connected. These remaining Participants who have not purchased connectivity are not forced or compelled to purchase connectivity, and they retain all of the other benefits of membership with the Exchange. Accordingly, Participants and non-Participants have the choice to purchase connectivity and are not compelled to do so in any way.

The Exchange believes that the proposed fees are fair, equitable and not unreasonably discriminatory because

[25] *See* IC–2018–15.

[26] These included past Participants who had terminated their membership with BOX and were no longer receiving BOX circulars, as well as third party network providers who were not on the Exchange's distribution list. The Exchange reached out to these firms individually to alert them of the upcoming fee change and give them the opportunity to disconnect any old connections to the BOX system.

[27] Currently, there are a total of 119 physical connections to BOX: 70 10 Gb connections and 49 non-10 Gb connections.

the connectivity pricing is directly related to the relative costs to BOX to provide those respective services and does not impose a barrier to entry to smaller participants. Accordingly, BOX offers various direct connectivity alternatives and various indirect connectivity (via third party) alternatives. BOX recognizes that there are various business models and varying sizes of market participants conducting business on BOX. The decision of which type of connectivity to purchase, or whether to purchase connectivity at all for a particular exchange, is based on the business needs of the firm. To assist prospective Participants or firms considering connecting to BOX, the Exchange provides information about BOX's available connectivity alternatives on the BOX website.[28] Section 2.4 of the BOX Connectivity Guide details the bandwidth requirements depending on the type of traffic each firm requires.

The non-10 Gb direct connectivity alternatives [29] are all comprised of bandwidth of equal to or less than 1 Gb and are purchased by market participants that require less bandwidth. For example, a firm requiring only simple order routing (which requires 128 kbps of bandwidth) would be satisfied with a non-10 Gb connection. Additionally, non-10 Gb connections can fully support both the sending of orders and the consumption of BOX's HSVF Data Feed.[30] By definition, non-10 Gb connections utilize less bandwidth and consume less resources from the network. Additionally, non-10 Gb connections and their interface modules cost considerably less than 10 Gb connections. Accordingly, because these connections consume the least resources of the Exchange and are the least costly for the Exchange to provide, the non-10 Gb connections are at a lower price point than the 10 Gb connections.[31]

In contrast, market participants that purchase 10 Gb connections utilize the most bandwidth and consume the most resources from the network.[32] The 10 Gb connection offers optimized connectivity with lower latency for latency sensitive participants and is faster in round trip time for connection oriented traffic to BOX than the non-10 Gb connection. In other words, 10 Gb connections carry ten times more gigabits than the non-10 Gb connection so information travelling over a 10 Gb connection will generally get to the destination faster than if it travelled over a non-10 Gb connection. As discussed herein, this lower latency is achieved through more advanced network equipment, such as advanced hardware and switching components, which translates to increased costs to BOX. A 10 Gb connection uses at least ten times the network infrastructure as the non-10 Gb connections as BOX has to scale the systems by the amount and size of all connections regardless of how they are used.[33] Accordingly, the Exchange believes that the allocation of the proposed fees ($1,000 per non-10 Gb connection and $5,000 per 10 Gb connection) are reasonable based on the resources consumed by the respective type of connection—lower resource consuming market participants pay the least, and highest resource consuming market participants pay the most, particularly since higher resource consumption translates to higher costs to BOX.[34]

Separately, the Exchange is not aware of any reason why market participants could not simply drop their connections and cease being BOX Participants if the Exchange were to establish unreasonable and uncompetitive price increases for its connectivity alternatives. Market participants choose to connect to a particular exchange and because it is a choice, BOX must set reasonable connectivity pricing, otherwise prospective participants would not connect and existing participants would disconnect or connect through a third-party reseller of connectivity. No options market participant is required by rule, regulation, or competitive forces to be a BOX Participant.[35] As evidence of the fact that market participants can and do disconnect from exchanges based on connectivity pricing, see the R2G Services LLC (''R2G'') letter based on BOX's proposed rule changes to increase its connectivity fees. The R2G letter stated, ''[w]hen BOX instituted a $10,000/month price increase for connectivity; we had no choice but to terminate connectivity into them as well as terminate our market data relationship. The cost benefit analysis just didn't make any sense for us at those new levels.'' [36] Accordingly, this example shows that if an exchange sets too high of a fee for connectivity and/or market data services for its relevant marketplace, market participants can choose to disconnect from the exchange. The Exchange notes that no other Participant or non-Participant disconnected from the exchange as a result of the connectivity fees.

Several market participants choose not to be BOX Participants and choose not to access BOX, and several market participants also access BOX indirectly through another market participant. If all market participants were required to be Participants of each exchange and connect directly to the exchange, all exchanges would have over 200 Participants, in line with Cboe's total membership.

[28] *See* BOX Connectivity Guide at *https://boxoptions.com/assets/NET-BX-001E-BOX-Network-Connection-Specifications-v2.7.pdf.*

[29] Non-10 Gb connectivity alternatives are comprised of protocol types that are at or under 1 Gb bandwidth. The protocol types are: Gigabit Ethernet, Ethernet, Fast Ethernet, Fiber Channel, OC–3, Singlemode Fiber, ISDN, POTS and T1.

[30] BOX's HSVF Data Feed does not require a 10 Gb physical connection. However, to receive the five best limits on the HSVF, a 10 Gb connection is required. On MIAX, the 1 Gb connection cannot support the consumption of the top of market data feed or the depth data feed product—both require a 10 Gb connection.

[31] Based on one trading day in January 2020, Participants with 10 Gb connections accounted for approximately 85% of message traffic over the network where Participants with non-10 Gb connections accounted for approximately 15% of message traffic over the network. As discussed herein, non-10 Gb connections consume less resources from the network and are therefore priced lower than the 10 Gb connection.

[32] Supporting a 10 Gb connection requires larger internal uplinks, firewalls and sniffer devices, all of which cost considerably more to maintain than support for non-10 Gb connections. Specifically, in order to support 10 Gb connections, BOX must obtain switches that offer 40Gb or more of uplink speed which cost more than the 1 Gb alternatives. In addition, BOX must obtain the appropriate connectors to support the 40Gb switches. These connectors are also more expensive than the 1 Gb alternatives. It is important to note that, as evidenced above, offering 10 Gb connections has downstream cost impacts as BOX needs to ensure that there is sufficient bandwidth internally in order to support multiple 10 Gb connections for Participants and non-Participants accessing the BOX system. The Exchange also notes that in addition to the higher cost of the internal 40Gb switches and appropriate connectors to support these connections, there are higher third party support contract costs in order to implement and maintain these technology components for the benefit of Participants and non-Participants who access the BOX system.

[33] The Exchange's network infrastructure requirements are based on the premise of all connections operating at full capacity.

[34] The IEX Comment Letter questioned if there were cost differentials between 10 Gb and non-10 Gb connections, stating that ''the hardware components to support a 10 Gb connection are essentially the same as those for a non-10 Gb connection . . . there may be marginally higher maintenance costs in the way of replacements or upgrades for a 10 Gb option, but IEX believes the difference in exchange cost for a 10 Gb connection will certainly be less than twice that of a higher latency connection.'' As described above, this is not true for BOX.

[35] Cboe Exchange Inc. has over 200 members, Nasdaq ISE, LLC has approximately 100 members, and NYSE American LLC has over 80 members. In comparison, the BOX has 51 Participants.

[36] The Exchange notes that R2G was a non-Participant service provider who connected to BOX at no cost and then sold BOX connectivity and market data to its customers. The $10,000 charge referenced in the R2G Letter was for two (2) 10 Gb connections.

The Exchange believes that its proposal is consistent with Section 6(b)(4) of the Act because the proposed fees allow the BOX to recover a portion of the costs incurred by BOX associated with maintaining and enhancing a state-of-the-art exchange network infrastructure in the US options industry. Additionally, there are significant costs associated with various projects and initiatives to improve overall network performance and stability, as well as costs paid to the third-party data centers for space rental, power used, etc.

The Exchange notes that unlike its competitors, BOX does not own its own data center and therefore cannot control data center costs. While some of the data center expenses are fixed, much of the expenses are not fixed, and thus increases as the number of physical connections increase. For example, new non-10 Gb and 10 Gb connections require the purchase of additional hardware to support those connections. Further, as the total number of all connections increase, BOX needs to increase their data center footprint and consume more power, resulting in increased costs charged by their third-party data center provider.

Further, as discussed herein, because the costs of operating a data center are significant and not economically feasible for BOX, BOX does not operate its own data centers, and instead contracts with a third-party data center provider. The Exchange notes that larger, dominant exchange operators own/operate their data centers, which offers them greater control over their data center costs. Because those exchanges own and operate their data centers as profit centers, BOX is subject to additional costs. Connectivity fees, which are charged for accessing the BOX's data center network infrastructure, are directly related to the network and offset such costs.

As detailed in the Exchange's and BOX Market's [37] 2018 audited financial statements which are publicly available as part of the Exchange's Form 1 Amendment BOX only has two sources of revenue that it can control: transaction fees and non-transactions fees.[38] Accordingly, BOX must cover all of its expenses from these two sources of revenue.

The Proposed Fees are fair and reasonable because they will not result in excessive pricing or supracompetitive profit, when comparing the total annual expense of the Exchange and BOX associated with providing the network connectivity services versus the total projected annual revenue of the Exchange [39] and BOX associated with providing the network connectivity services.

The Exchange conducted an extensive review of the Exchange and BOX expenses to determine whether such expenses relate to the provision of network connectivity services, and, if such expense did so relate, what portion of such expense actually supports the provision of network connectivity services, and thus bears a relationship that is, ''in nature and closeness,'' directly related to network connectivity services. The sum of all such portions of expenses represents the total actual baseline cost of the Exchange and BOX to provide network connectivity services.

For 2018, the annual expense for BOX and the Exchange associated with providing the network connectivity services was approximately $8.9 million. This amount is comprised of both direct and indirect expenses. The financial information below is meant to provide greater detail and clarity concerning BOX's cost allocations as they pertain to expenses for network connectivity services; and further describe the nature and closeness of the relationship between the identified costs and connectivity services where possible.

The direct expense (which relates to the network infrastructure, associated data center processing equipment required to support various connections, network monitoring systems and associated software required to support the various forms of connectivity) was approximately $6.4 million.[40] The Exchange notes the $6.4 million direct expense is only a portion of the overall technology costs for BOX and the Exchange. The $6.4 million direct expense does not include technology items such as the Exchange and BOX technological improvements and upkeep to the BOX trading and matching system,[41] third party technology security expenses for the BOX trading and matching system, technology license contract costs for the BOX trading and matching system, and third party billing expenses associated with the BOX trading and matching system. Further, the direct expense of $6.4 million does not include the indirect expenses detailed below. A more detailed breakdown of the direct annual operational expense in 2018 includes the following:

- Over $2.8 million for space rental, power usage, connections, etc. at the Exchanges data centers; [42]
- Over $1.1 million for data center support and management of third party vendors; [43]

[37] BOX Exchange LLC (''Exchange'') and BOX Options Market LLC (''BOX'') are two different entities. The Exchange is a national securities exchange registered with the SEC under Section 6 of the Securities Exchange Act of 1934. The Exchange fulfills the regulatory functions and responsibilities and oversees BOX, the equity options market. Expenses associated with network connectivity services are born by both the Exchange and BOX. A summary of the Form 1 Statement of Income and Expense for both the Exchange and BOX is included as an Exhibit 3 of this filing. The Exchange notes that the Non-Transaction Fees for BOX Options Market LLC are now broken down further into three additional categories: Access Fees, Market Data Fees, and Participant Fees.

[38] Options Price Authority Reporting (''OPRA'') income is not controlled by BOX.

[39] Revenues for the Exchange are limited to the Options Regulatory Fee (''ORF'') and fines and disgorgements.

[40] Direct connectivity expenses are a portion of the following line items in the BOX and Exchange Form 1 Financial Statements: Technical and Operational, Other and Communications and Data Processing. The Exchange notes that these direct expenses include all expenses associated with the Exchanges' data centers. BOX's infrastructure design does not distinguish network connectivity expenses from other data center expenses. In other words, network connectivity is intertwined with the overall infrastructure of the BOX system.

[41] In determining the $6.4 million direct cost for network connectivity, the Exchange did not include any expenses related to business development initiatives. For example, the technological cost for adding complex order functionality to certain order types would not be included in the technological improvement costs outlined in the direct expense for network connectivity. The total cost for technological improvements in 2018, including business development initiatives and other initiatives not related to network connectivity was $3.86 million.

[42] This cost can be found in three line items in the Statement of Income of the BOX and Exchange Form 1 documents: ''Professional Services: Other,'' ''Professional Services: Technical and Operational''; and ''Communications and data processing.'' The Exchange notes that the $2.8 million figure includes, but is not limited to, the fees paid to: Equinix and 365 Services LLC, the data centers that host the Exchange's network infrastructure, Secure Financial Transaction Infrastructure (''SFTI''), which supports connectivity and fees for the entire US options industry, various other service providers (including Cogent, Lightower and Activ Financial Systems, Inc) which provide content, connectivity services, and infrastructure services for critical components of options connectivity; and various other hardware and software providers which support the production environment in which Participants and non-Participants connect to the network to trade, receive market data, etc. The Exchange believes that without the technology services of the all providers discussed above, the Exchange would not be able to operate and support the BOX network and provide network connectivity services to Participants and non-Participants. The Exchange believes that including the costs of these services is reasonable as they represent the Exchange's cost to operate and support the BOX network and ultimately provide optimal network connectivity to market participants.

[43] These costs include annual service and support contracts with a large number of third party vendors to support the data centers and trading platform. These costs appear in the ''Professional Services: Technical and Operational'' line item of the Statement of Income of the BOX and Exchange Form 1 documents.

• Over $700,000 in technological improvements to the data center infrastructure; [44]

• Over $1.4 million for resources for technical and operational services for the Exchange's data centers; [45] and

• $400,000 in market data connectivity fees.[46]

The indirect expense (which includes expense from such areas as trading operations, software development, business development, information technology, marketing, human resources, legal and regulatory, finance and accounting) that the Exchange and BOX allocate to the maintenance and support of network connectivity services was approximately $2.5 million.[47] Included in this indirect expense total are the following:

• Over $1 million in employee compensation and benefits for full-time employees that support network connectivity services; [48]

• Over $1 million in software and hardware depreciation; [49]

• Over $100,000 in office space and rent to support employees related to network connectivity; [50] and

• Over $200,000 in miscellaneous data, communications, external IT, and regulatory audit costs relate to expenses that support general connectivity for trading and personnel support.[51]

Total projected annualized revenue associated with selling the network connectivity services (reflecting the proposed fees on a fully-annualized basis, using July 2019 data) for BOX is projected to be approximately $4.6 million. This projected revenue amount of $4.6 million represents approximately 13% of total net revenue of BOX and Exchange for 2018 of approximately $35.5 million. The Exchange believes that an indirect expense allocation of 10% of total expense (less direct expense) to network connectivity services is fair and reasonable, as total projected network connectivity revenue represents approximately 13% of total net revenue for 2018. That is, direct expense of $6.4 million plus indirect expense of $2.5 million fairly reflects the total annual expense associated with providing the network connectivity services, both from the perspective of similar revenue and expense percentages (connectivity to total), as well as matching connectivity resources to connectivity expenses. The Exchange believes that this is a conservative allocation of indirect expense. Accordingly, the total projected connectivity revenue for BOX, reflective of the proposed fees, on an annualized basis, of $4.6 million, is almost half of the total annual actual BOX and Exchange connectivity expense (direct and indirect) for 2018 of $8.9 million. Further, even the direct expense associated with providing network connectivity ($6.4 million) exceeds expected revenue from connectivity.

The Exchange projects comparable network connectivity revenue and expense for 2020 for BOX. Accordingly, the Proposed Fees are fair and reasonable because they do not result in excessive pricing or supracompetitive profit, when comparing the actual network connectivity costs to the Exchange and BOX versus the projected network connectivity annual revenue. Additional information on overall revenue and expense can be found in the Exchange's and BOX's 2018 audited financial results, which is publicly available as part of the Exchange's Form 1 filed with the Commission.

For the avoidance of doubt, none of the expenses included herein relating to the provision of network connectivity services relate to the provision of any other services offered by BOX. Stated differently, no expense amount of the Exchange or BOX is allocated twice.

The Exchange again notes that other exchanges have similar connectivity alternatives for their participants, including similar low-latency connectivity. For example, Nasdaq PHLX LLC (''Phlx''), NYSE Arca, Inc. (''Arca''), NYSE American LLC (''NYSE American'') and Nasdaq ISE, LLC (''ISE'') all offer a 1 Gb, 10 Gb and 10 Gb low latency ethernet connectivity alternatives to each of their participants.[52] The Exchange further notes that Phlx, ISE, Arca and NYSE American each charge higher rates for such similar connectivity to primary and secondary facilities.[53]

The financials above show that BOX has incurred substantial costs associated with maintaining and enhancing the BOX network. These costs, coupled with BOX's historically low transaction fees, place BOX at a competitive disadvantage against other options exchanges who charge connectivity fees to market participants. BOX has no choice but to begin charging Participants and non-Participants fees for connecting directly to the network which BOX has taken considerable measures to maintain and enhance for the benefit of those Participants and non-Participants in order to remain competitive with the other options exchanges in the industry.

Finally, the Exchange believes redefining the HSVF Connection Fee as a Port Fee is reasonable, equitable and not unfairly discriminatory. This classification is more accurate because an HSVF subscription is not enabled

[44] This cost is represented on the BOX's Financial Statement document under the ''Computer equipment and software and leasehold improvements'' line item. The associated amortization in 2018 was excluded from the indirect depreciation outlined herein.

[45] These costs are included in the ''Professional Services: Technical and Operational'' line item of the Statement of Income of the BOX and Exchange Form 1 documents.

[46] A portion can be tied to the ''Communications and data processing'' line item of the BOX and Exchange Statement of Income. The remaining portion is in the ''Professional Services: Other'' line item of the BOX and the Exchange Statement of Income. Of note, regarding market data connectivity fees, this is the cost associated with BOX consuming connectivity/content from the equities markets in order to operate the Exchange, causing BOX to effectively pay its competitors for this connectivity.

[47] Indirect expenses for connectivity are a portion of the following line items in the BOX and Exchange Form 1 Financial Statements: Employee, facilities, and other, Depreciation and Amortization, Consulting and Financial and Administrative. The Exchange notes that these indirect expenses represent approximately 10% of the total annual expenses for BOX and the Exchange in 2018.

[48] This cost includes employees in network operations, trading operations, development, system operations, business, etc., as well as staff in general corporate departments (such as legal, regulatory, and finance) that support those employees and functions. BOX's employee compensation and benefits expense relating to providing network connectivity services was a portion of the total expense for employee compensation and benefits that is stated in the Employee, facilities, and other line item in the 2018 Financial Statements for BOX and the Exchange.

[49] This cost includes depreciation and amortization of hardware and software used to provide network connectivity services, including equipment, servers, cabling, purchased software and internally developed software used in the production environment to support the provision of network connectivity for trading. BOX's depreciation and amortization expense relating to providing network connectivity services was a portion of the total expense for depreciation and amortization that is stated in the 2018 Financial Statements for BOX and the Exchange.

[50] This cost includes occupancy costs for leased office space for staff that support the provision of network connectivity services. BOX and Exchange's combined occupancy expense relating to providing network connectivity services is a portion of the total expense for occupancy that is stated in the Employee, facilities, and other line item in the 2018 Financial Statements for BOX and the Exchange.

[51] The combined miscellaneous expense relating to trading connectivity and personnel support was a portion of multiple line items in the 2018 Financial Statements for BOX and the Exchange.

[52] *See* Phlx and ISE Rules, General Equity and Options Rules, General 8, Section 1(b). Phlx and ISE each charge a monthly fee of $2,500 for each 1 Gb connection, $10,000 for each 10 Gb connection and $15,000 for each 10 Gb Ultra connection, which the equivalent of the Exchange's 10 Gb ULL connection. *See also* NYSE American Fee Schedule, Section V.B, and Arca Fees and Charges, Co-Location Fees. NYSE American and Arca each charge a monthly fee of $5,000 for each 1 Gb circuit, $14,000 for each 10 Gb circuit and $22,000 for each 10 Gb LX circuit, which the equivalent of the Exchange's 10 Gb ULL connection.

[53] *Id.*

through a physical connection to the Exchange. Although market participant must be credentialed by BOX to receive the HSVF, anyone can become credentialed by submitting the required documentation.[54] The Exchange does not propose to alter the amount of the existing HSVF fee; subscribers to the HSVF will continue to pay $1,500 per month. As with the Connectivity Fees, BOX's HSVF Port Fee is in line with industry practice.[55]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange does not believe that the proposed rule change would place certain market participants at the Exchange at a relative disadvantage compared to other market participants or affect the ability of such market participants to compete. In particular, the Exchange has received no official complaints from Participants that purchase the Exchange's connectivity that the Exchange's fees or the Proposed Fees are negatively impacting or would negatively impact their abilities to compete with other market participants or that they are placed at a disadvantage.[56] The Exchange believes that the Proposed Fees do not place certain market participants at a relative disadvantage to other market participants because the connectivity pricing is associated with relative usage of the various market participants and does not impose a barrier to entry to smaller participants. As described above, the less expensive non-10 Gb direct connection is generally purchased by market participants that utilize less bandwidth. The market participants that purchase 10 Gb connections utilize the most bandwidth, and those are the participants that consume the most resources from the network. Accordingly, the Proposed Fees do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation of the Proposed Fees reflect the network resources consumed by the various size of market participants—lowest bandwidth consuming members pay the least, and highest bandwidth consuming members pays the most, particularly since higher bandwidth consumption translates to higher costs to BOX.

Inter-Market Competition

The Exchange believes the Proposed Fees do not place an undue burden on competition on other SROs that is not necessary or appropriate. In particular, options market participants are not forced to connect to (and purchase market data from) all options exchanges, as shown by the number of Participants of BOX as compared to the much greater number of members at other options exchanges (as described above). Not only does BOX have less than half the number of Participants as certain other options exchanges, but there are also a number of the Exchange's Participants that do not connect directly to BOX. Additionally, the Exchange notes other exchanges have similar connectivity alternatives for their participants, including similar low-latency connectivity, but with much higher rates to connect.[57] The Exchange is also unaware of any assertion that its existing fee levels or the Proposed Fees would somehow unduly impair its competition with other options exchanges. To the contrary, if the fees charged are deemed too high by market participants, they can simply disconnect.

Unilateral action by the Exchange in establishing fees for services provided to its Participants and others using its facilities will not have an impact on competition. As a small exchange in the already highly competitive environment for options trading, the Exchange does not have the market power necessary to set prices for services that are unreasonable or unfairly discriminatory in violation of the Exchange Act. The Exchange's proposed fees, as described herein, are comparable to and generally lower than fees charged by other options exchanges for the same or similar services. Lastly, the Exchange believes the proposed change will not impose a burden on intramarket competition as the proposed fees are applicable to all Participants and others using its facilities that connect to BOX.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Exchange Act[58] and Rule 19b–4(f)(2) thereunder,[59] because it establishes or changes a due, or fee.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or would otherwise further the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BOX–2020–03 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–BOX–2020–03. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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

[54] *See Trading Interface Specification,* BOX Options, *https://boxoptions.com/technology/trading-interface-specifications/.*

[55] See Cboe Data Services, LLC (CDS) Fee Schedule § VI (charging $500 per month for up to five users to access the Enhanced Controlled Data Distribution Program).

[56] The Exchange notes that it did receive one complaint from a non-Participant third party that, prior to the proposed fees, received connectivity for free and resold it to other market participants. This non-Participant ceased connectivity to the Exchange in January 2019.

[57] *See supra* note 20.

[58] 15 U.S.C. 78s(b)(3)(A)(ii).

[59] 17 CFR 240.19b–4(f)(2).

Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BOX–2020–03, and should be submitted on or before March 10, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[60]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–03091 Filed 2–14–20; 8:45 am]

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[60] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88158; File No. SR–CFE–2020–001]

Self-Regulatory Organizations; Cboe Futures Exchange, LLC; Notice of Filing of a Proposed Rule Change Regarding Quoting Functionality

February 11, 2020.

Pursuant to Section 19(b)(7) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on January 29, 2020 Cboe Futures Exchange, LLC (''CFE'' or ''Exchange'') 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 by CFE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons. CFE also has filed this proposed rule change with the Commodity Futures Trading Commission (''CFTC''). CFE filed a written certification with the CFTC under Section 5c(c) of the Commodity Exchange Act (''CEA'')[2] on January 29, 2020.

[1] 15 U.S.C. 78s(b)(7).

I. Self-Regulatory Organization's Description of the Proposed Rule Change

The Exchange proposes to specify the information that is required to be included within a Bulk Message and within a Quote in connection with the implementation of quoting functionality on CFE's trading system (''CFE System'').

The scope of this filing is limited solely to the application of the rule amendments to security futures that may be traded on CFE. Although no security futures are currently listed for trading on CFE, CFE may list security futures for trading in the future.

CFE is making the rule amendments included in this proposed rule change in conjunction with other rule amendments being made by CFE in connection with its implementation of quoting functionality that are not required to be submitted to the Commission pursuant to Section 19(b)(7) of the Act[3] and thus are not included as part of this rule change.

The rule amendments included as part of this proposed rule change are to apply to all products traded on CFE, including both non-security futures and any security futures that may be listed for trading on CFE. CFE is submitting these rule amendments to the Commission under Section 19(b)(7) of the Act[4] because they relate to reporting requirements that would apply with respect to any security futures that may be traded on CFE.

The text of the proposed rule change is attached as Exhibit 4 to the filing but is not attached to the publication of this notice.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, CFE 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. CFE has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[2] 7 U.S.C. 7a–2(c).

[3] 15 U.S.C. 78s(b)(7).

[4] 15 U.S.C. 78s(b)(7).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

CFE Trading Privilege Holders (''TPHs'') currently utilize match capacity allocations to submit Orders to the CFE System. These match capacity allocations may be used for the submission of single Orders to the CFE System utilizing either the Financial Information Exchange (''FIX'') or Binary Order Entry (''BOE'') protocol. A single Order refers to an Order that is submitted to the CFE System through a message type that may include one Order in each message. Going forward, these match capacity allocations will be referred to as order match capacity allocations.

In connection with the implementation of quoting functionality on the CFE System, CFE will provide all TPHs with the option to use order match capacity allocations and/or quoting match capacity allocations. A quoting match capacity allocation is an additional type of match capacity allocation that will provide the ability to submit single Orders and Bulk Messages to the CFE System utilizing the BOE protocol. A Bulk Message is a new message type that may be utilized to submit multiple Quotes to the CFE System in a single message. A Quote refers to the entry, modification, or cancellation of a bid or offer for a CFE Contract through a Bulk Message. A Quote will be treated the same as an Order, and the term ''Order'' encompasses a Quote, unless the Exchange rules specify otherwise.

CFE Rule 403 (Order Entry and Maintenance of Front-End Audit Trail Information) currently requires that Orders contain specified information and that Orders that do not contain this information are rejected or canceled back to the sender. CFE is proposing to modify Rule 403 to provide that these existing provisions apply to single Orders, to set forth the information that is required to be included within a Bulk Message and within a Quote, and to provide that Bulk Messages and Quotes that do not contain the required information will be rejected or canceled back to the sender.

Specifically, CFE is proposing to amend Rule 403 in the following ways:

Rule 403(a) currently provides, in pertinent part, that each Order must contain the following information: (i) Whether such Order is a buy or sell Order; (ii) Order type; (iii) price or premium (if the Order is not a Market Order); (iv) quantity; (v) Contract

identifier or product and contract expiration(s); (vi) Client Order ID; (vii) Executing Firm ID (''EFID''); (viii) Order Entry Operator ID; (ix) Clearing Corporation origin code (C for Customer or F for Firm); (x) Customer Type Indicator code; (xi) manual Order indicator; (xii) account designation (which is the account number of the account of the party for which the Order was placed, except that a different account designation may be included in the case of a bunched Order or in the case of an Order for which there will be a post-trade allocation of the resulting trade(s) to a different clearing member); (xiii) in the case of Orders for Options, either Contract identifier or each of strike price, type of option (put or call) and expiration; and (xiv) such additional information as may be prescribed from time to time by the Exchange. CFE is proposing to move the above provisions from current Rule 403(a) to new Rule 403(b) and to provide in new Rule 403(b) that the above provisions will apply to single Orders.

CFE is proposing to add new Rule 403(c) to provide that each Bulk Message must contain the following information: (i) Quote Update ID; (ii) EFID; (iii) Order Entry Operator ID; (iv) Clearing Corporation origin code (C for Customer or F for Firm); (iv) Customer Type Indicator code; (v) manual Order indicator; (vi) account designation (which shall be the account number of the account of the party for which the Quotes in the Bulk Message were placed, except that a different account designation may be included in the case of a Quote that is a bunched Order or in the case of a Quote for which there will be a post-trade allocation of the resulting trade(s) to a different clearing member); (vii) at least one Quote; and (vii) such additional information as may be prescribed from time to time by the Exchange.

CFE is proposing to add new Rule 403(d) to provide that each Quote must contain the following information: (i) Whether the Quote is to buy or sell; (ii) price or premium; (iii) quantity; (iv) Contract identifier; and (v) such additional information as may be prescribed from time to time by the Exchange.

Rule 403(a) currently provides that any Order that does not contain required information in a form and manner prescribed by the Exchange will be rejected or canceled back to the sender by the CFE System. CFE is proposing to delete that provision from Rule 403(a) and to add an equivalent provision to new Rule 403(e) that will apply to single Orders, Bulk Messages, and Quotes. Specifically, CFE proposes that new Rule 403(e) provide that any single Order, Bulk Message, or Quote that does not contain required information in a form and manner prescribed by the Exchange will be rejected or canceled back to the sender by the CFE System.

Finally, CFE is proposing to change the paragraph lettering of current Rule 403(b) to Rule 403(f) and to change the paragraph lettering of current Rule 403(c) to Rule 403(g) without changing the text of either provision.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Sections 6(b)(1)[6] and 6(b)(5)[7] in particular in that it is designed:

- To enable the Exchange to enforce compliance by its TPHs and persons associated with its TPHs with the provisions of the rules of the Exchange,
- to prevent fraudulent and manipulative acts and practices,
- to promote just and equitable principles of trade,
- to foster cooperation and coordination with persons engaged in facilitating transactions in securities,
- to remove impediments to and perfect the mechanism of a free and open market and a national market system,
- and in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change serves to enhance CFE's market by contributing to CFE's ability to implement quoting functionality by requiring the provision of information that the CFE System needs in order to process Bulk Messages and Quotes submitted through that quoting functionality.

The Exchange also believes that the proposed rule change serves to strengthen CFE's ability to carry out its responsibilities as a self-regulatory organization. First, the proposed rule change provides guidance to TPHs regarding the type of information that must be included within Bulk Messages and Quotes. Second, the proposed rule change contributes to enhancing the effectiveness of CFE's audit trail program by helping to assure that required information is included within Bulk Messages and Quotes. Third, the proposed rule change furthers CFE's ability to enforce compliance with CFE rules since the Exchange plans to utilize this audit trail information in connection with its surveillance of CFE's market and in connection with reviewing trading activity on CFE's market for rule compliance.

B. Self-Regulatory Organization's Statement on Burden on Competition

CFE does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act, in that the proposed rule change will enhance CFE's ability to carry out its responsibilities as a self-regulatory organization. The Exchange believes that the proposed rule change is equitable and not unfairly discriminatory in that the rule amendments included in the proposed rule change would apply equally to all TPHs.

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 proposed rule change will become operative on February 12, 2020. At any time within 60 days of the date of effectiveness of the proposed rule change, the Commission, after consultation with the CFTC, may summarily abrogate the proposed rule change and require that the proposed rule change be refiled in accordance with the provisions of Section 19(b)(1) of the Act.[8]

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–CFE–2020–001 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(1).

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78s(b)(1).

Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CFE–2020–001. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change 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–CFE–2020–001, and should be submitted on or before March 10, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–03088 Filed 2–14–20; 8:45 am]

BILLING CODE 8011–01–P

[9] 17 CFR 200.30–3(a)(73).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88162; File No. SR–NSCC–2019–801]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of No Objection To Advance Notice To Enhance National Securities Clearing Corporation's Haircut-Based Volatility Charge Applicable to Municipal Bonds

February 11, 2020.

On December 13, 2019, National Securities Clearing Corporation (''NSCC'') filed with the Securities and Exchange Commission (''Commission'') advance notice SR–NSCC–2019–801 (''Advance Notice'') pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, entitled Payment, Clearing and Settlement Supervision Act of 2010 (''Clearing Supervision Act'')[1] and Rule 19b–4(n)(1)(i)[2] under the Securities Exchange Act of 1934 (''Exchange Act''[3] to revise NSCC's methodology for calculating margin amounts applicable to municipal bonds. The Advance Notice was published for public comment in the **Federal Register** on January 14, 2020,[4] and the Commission has received no comments regarding the changes proposed in the Advance Notice.[5] This publication serves as notice of no objection to the Advance Notice.

I. The Advance Notice

The proposals reflected in the Advance Notice would revise NSCC's Rules and Procedures (''Rules'')[6] to change the methodology NSCC uses for calculating the haircut-based margin charge applicable to municipal bonds.

A. Background

NSCC provides clearing, settlement, risk management, central counterparty services, and a guarantee of completion for virtually all broker-to-broker trades involving equity securities, corporate and municipal debt securities, and certain other securities. NSCC manages its credit exposure to its members by determining an appropriate Required Fund Deposit (*i.e.,* margin) for each member.[7] The aggregate of all NSCC members' Required Fund Deposits (together with certain other deposits required under the Rules) constitute NSCC's Clearing Fund, which NSCC would access should a defaulting member's own Required Fund Deposit be insufficient to satisfy losses to NSCC caused by the liquidation of the defaulting member's portfolio.[8] NSCC collects each member's Required Fund Deposit to mitigate potential losses to NSCC associated with the liquidation of the member's portfolio in the event of the member's default.[9]

Each member's Required Fund Deposit consists of a number of applicable components, which are calculated to address specific risks that the member's portfolio presents to NSCC.[10] Generally, the largest component of a member's Required Fund Deposit is the volatility component.[11] The volatility component is designed to calculate the potential losses on a portfolio over a given period of time assumed necessary to liquidate the portfolio, within a 99% confidence level.

The methodology for calculating the volatility component of the Required Fund Deposit depends on the type of security.[12] Specifically, for certain

[1] 12 U.S.C. 5465(e)(1).

[2] 17 CFR 240.19b–4(n)(1)(i).

[3] 15 U.S.C. 78a *et seq.*

[4] Securities Exchange Act Release No. 87911 (January 8, 2020), 85 FR 2197 (January 14, 2020) (File No. SR–NSCC–2019–801) (''Notice of Filing''). On December 13, 2019, NSCC also filed a related proposed rule change (SR–NSCC–2019–004) with the Commission pursuant to Section 19(b)(1) of the Exchange Act and Rule 19b–4 thereunder (''Proposed Rule Change''). *See* 15 U.S.C. 78s(b)(1) and 17 CFR 240.19b–4 respectively. In the Proposed Rule Change, which was published in the **Federal Register** on January 2, 2020, NSCC seeks approval of proposed changes to its rules necessary to implement the Advance Notice. Securities Exchange Act Release No. 87858 (December 26, 2019), 85 FR 149 (January 2, 2020). The comment period for the related Proposed Rule Change filing closed on January 23, 2020, and the Commission received no comments.

[5] As the proposal contained in the Advance Notice was also filed as a proposed rule change, all public comments received on the proposal are considered regardless of whether the comments are submitted on the proposed rule change or the Advance Notice.

[6] Capitalized terms not defined herein are defined in the Rules, *available at http://dtcc.com/~/media/Files/Downloads/legal/rules/nscc_rules.pdf.*

[7] *See* Rule 4 (Clearing Fund) and Procedure XV (Clearing Fund Formula and Other Matters) of the Rules (''Procedure XV''), *supra* note 6.

[8] *See id.*

[9] The Rules identify when NSCC may cease to act for a member and the types of actions NSCC may take. For example, NSCC may suspend a firm's membership with NSCC or prohibit or limit a member's access to NSCC's services in the event that member defaults on a financial or other obligation to NSCC. *See* Rule 46 (Restrictions on Access to Services) of the Rules, *supra* note 6.

[10] Procedure XV, *supra* note 6.

[11] *See id.*

[12] For most securities (*e.g.,* equity securities), NSCC calculates the volatility component as the greater of (1) the larger of two separate calculations that utilize a parametric Value at Risk (''VaR'') model, (2) a gap risk measure calculation based on the largest non-index position in a portfolio that exceeds a concentration threshold, which addresses concentration risk that can be present in a member's portfolio, and (3) a portfolio margin floor calculation based on the market values of the long

securities, including municipal bonds, NSCC calculates a haircut-based volatility component by multiplying the absolute value of a member's positions in such securities by a certain percentage designated by NSCC.[13]

NSCC's current methodology for designating the percentages used in calculating the haircut-based volatility component for municipal bonds involves distinguishing between municipal bonds based on tenor (*i.e.,* remaining time to maturity), municipal sector (*e.g.,* general obligation, transportation, healthcare, etc.), and credit rating.[14] Pursuant to that methodology, NSCC assigns each tenor-based group a percentage.[15] For municipal bonds rated higher than BBB+, the tenor-based percentage is the percentage NSCC uses to calculate the haircut-based volatility component.[16] However, for municipal bonds rated BBB+ or lower, NSCC multiplies the tenor-based percentage by a sector-based risk factor, resulting in a larger percentage for the haircut.[17] The additional sector-based risk factors account for the variable risks between municipal sectors associated with the various industries in which the bonds are issued and the sources of bond repayment.[18]

In all cases, the percentage used to calculate the municipal bond haircut-based volatility component is not less than 2%, regardless of a municipal bond's credit rating.[19]

B. New Changes to NSCC's Methodology for Calculating Municipal Bond Haircut Percentages

NSCC states that it regularly assesses its margining methodologies to evaluate whether margin levels are commensurate with the particular risk attributes of the various products, portfolios, and markets that NSCC serves.[20] NSCC further states that based on recent impact studies, the margin levels generated from municipal bonds using the current methodology exceed the levels necessary to mitigate the risk associated with those securities.[21] In the Advance Notice, NSCC proposes to change the methodology for calculating the municipal bond haircut-based volatility component so that the amount of margin NSCC collects is more commensurate with the risk attributes of those securities.

As proposed in the Advance Notice, NSCC would retain the current provision that in all cases the percentage used to calculate the municipal bond haircut-based volatility component is not less than 2%, regardless of a municipal bond's credit rating. NSCC would also continue to distinguish between municipal bonds based on tenor, credit rating, and municipal sector. However, NSCC would calculate the haircut percentages for various groups of municipal bonds based on the historical returns of one or more benchmark indices over a look-back period not shorter than 10 years, using a minimum 99% calibration percentile.

The proposal would change the manner in which NSCC addresses the risk presented by lower-rated municipal bonds. Instead of the current methodology's approach which applies a sector-based straight risk factor to the tenor-based haircut, resulting in a larger haircut percentage, the proposed approach would allow the calculation to be more precisely tailored to the risks presented by particular municipal bonds. Specifically, the new approach would base the haircut percentage on the historical returns of one or more benchmark indices, such as tenor-based indices, municipal bond sector-based indices, and high-yield indices, over a look-back period of at least ten years and would no longer use a sector-based straight risk factor for lower-rated municipal bonds. This approach should allow NSCC to more accurately calculate margin amounts appropriate for the risks presented by such municipal bonds by allowing NSCC to take into account a broader range of risk characteristics associated with municipal bonds. NSCC notes that, based on recent impact studies comparing the current and proposed methodologies, the proposed methodology would manage NSCC's applicable risks well above the 99% confidence level, although it would generate lower overall margin amounts.[22]

Under the proposal in the Advance Notice, NSCC states that for municipal bonds rated higher than BBB+, NSCC would use a tenor-based index as the applicable benchmark index.[23] Specifically, NSCC would use the percentage derived from the tenor-based index as the haircut for the purpose of calculating the volatility component for municipal bonds rated higher than BBB+.[24] For municipal bonds rated BBB+ or lower (or not rated), NSCC states that it would use a percentage that is the highest of: (1) The applicable tenor-based index, (2) municipal bond sector-based indices, and (3) a high-yield index. [25] For all municipal bonds, when deriving the haircut percentage from the applicable indices, NSCC would use a look-back period of a 10 year rolling window plus a 1-year ''worst case scenario'' stress period.[26] NSCC would identify the largest 3-day price return movement (reflected as a percentage) within the 99th percentile of all 3-day price return movements during the look-back period. Additionally, NSCC proposes to re-calibrate the municipal bond haircut percentages no less frequently than annually.

As proposed in the Advance Notice, NSCC would have the ability to modify certain aspects of the application of the proposed methodology consistent with NSCC's applicable governance procedures and based on NSCC's determination that such modifications are necessary to manage the applicable risks above the 99% confidence level. Specifically, based on NSCC's regular review of its margin methodologies, NSCC would be able to modify: The frequency of re-calibrating the municipal bond haircut percentages; applicable benchmark indices and the applicable period for the price return

and short positions in the portfolio, which addresses risks that might not be adequately addressed with the other volatility component calculations. *See id.; see also* Securities Exchange Act Release No. 82780 (February 26, 2018), 83 FR 9035 (March 2, 2018) (File No. SR–NSCC–2017–808); Securities Exchange Act Release No. 82781 (February 26, 2018), 83 FR 9042 (March 2, 2018) (File No. SR–NSCC–2017–020).

[13] Procedure XV, *supra* note 6.

[14] Notice of Filing, *supra* note 4 at 2198.

[15] *See id.*

[16] For example, a $10MM short position in a municipal bond rated above BBB+ with 3 years to maturity is subject to the 2–5 years tenor-based group haircut of 5%, which applies to the absolute market value of the positions, resulting in a haircut-based volatility component of $500,000. Notice of Filing, *supra* note 4 at 2198.

[17] For example, a $10MM short position in a healthcare sector municipal bond rated BBB+ or lower with 3 years to maturity is subject to the 2–5 years tenor-based group haircut (5%) multiplied by the sector-based factor of 1.2, resulting in a 6% haircut-based volatility component of $600,000. Notice of Filing, *supra* note 4 at 2198.

[18] *See id.*

[19] Procedure XV, *supra* note 6.

[20] Notice of Filing, *supra* note 4 at 2198.

[21] As part of the Advance Notice, NSCC filed Exhibit 3—NSCC Impact Studies, comparing the current and proposed methodologies. Pursuant to 17 CFR 240.24b–2, NSCC requested confidential treatment of Exhibit 3.

[22] Notice of Filing, *supra* note 4 at 2199.

[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] NSCC believes that a 10-year window plus 1-year stress period would capture relevant data and cover sufficient market data without diluting the ''tail'' with an abundance of data. NSCC believes this look-back period is typically long enough to capture at least two recent market cycles, whereas a longer look-back period might ''flatten'' out the results because recent volatile periods might be offset by non-volatile periods, making the more recent volatility appear less significant. Notice of Filing, *supra* note 4 at 2199.

used in the calculations; and the look-back period. NSCC states that any such modifications would be subject to the governance procedures applicable to all of NSCC's margin methodologies, as set forth in NSCC's Clearing Agency Model Risk Management Framework, which the Commission has approved.[27]

Finally, NSCC proposes a method to address extraordinary circumstances in which a certain municipality or issuer may present unique risks not otherwise captured by the proposed methodology's use of a percentage derived from the maximum of the applicable tenor-based index, municipal bond sector-based indices, and high-yield indices.[28] In such scenarios, NSCC proposes to have the ability to use the highest percentage generated for any municipal bond group when calculating the haircut-based volatility component for municipal bonds issued by the municipality or issuer presenting such unique risks.

II. Discussion and Commission Findings

Although the Clearing Supervision Act does not specify a standard of review for an advance notice, the stated purpose of the Clearing Supervision Act is instructive: to mitigate systemic risk in the financial system and promote financial stability by, among other things, promoting uniform risk management standards for SIFMUs and strengthening the liquidity of SIFMUs.[29]

Section 805(a)(2) of the Clearing Supervision Act authorizes the Commission to prescribe regulations containing risk management standards for the payment, clearing, and settlement activities of designated clearing entities engaged in designated activities for which the Commission is the supervisory agency.[30] Section 805(b) of the Clearing Supervision Act provides the following objectives and principles for the Commission's risk management standards prescribed under Section 805(a):[31]

- To promote robust risk management;
- to promote safety and soundness;
- to reduce systemic risks; and
- to support the stability of the broader financial system.

Section 805(c) provides, in addition, that the Commission's risk management standards may address such areas as risk management and default policies and procedures, among others areas.[32]

The Commission has adopted risk management standards under Section 805(a)(2) of the Clearing Supervision Act and Section 17A of the Exchange Act (the ''Clearing Agency Rules'').[33] The Clearing Agency Rules require, among other things, each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures that are reasonably designed to meet certain minimum requirements for its operations and risk management practices on an ongoing basis.[34] As such, it is appropriate for the Commission to review advance notices against the Clearing Agency Rules and the objectives and principles of these risk management standards as described in Section 805(b) of the Clearing Supervision Act. As discussed below, the Commission believes the proposal in the Advance Notice is consistent with the objectives and principles described in Section 805(b) of the Clearing Supervision Act,[35] and in the Clearing Agency Rules, in particular Rules 17Ad–22(e)(4) and (e)(6).[36]

A. Consistency With Section 805(b) of the Clearing Supervision Act

The Commission believes that the Advance Notice is consistent with the stated objectives and principles of Section 805(b) of the Clearing Supervision Act.

As described above in Section I.A., NSCC's current methodology calculates municipal bond haircut percentages using tenor-based percentages and sector-based risk factors. NSCC states that the current methodology generates margin amounts greater than necessary to mitigate NSCC's risks associated with municipal bonds. NSCC proposes to replace the current methodology with one that would calculate the haircut percentages based on the historical returns of one or more benchmark indices over a look-back period of not shorter than 10 years, using a minimum 99% calibration percentile. These changes would result in margin amounts that are more commensurate with the risk attributes of municipal bonds, while still managing NSCC's applicable risks well above the 99% confidence level.[37] Accordingly, the Commission believes that the proposed methodology for calculating municipal bond haircut percentages would be consistent with promoting robust risk management because the proposed methodology would enable NSCC to more precisely manage the relevant risks than the current methodology.

Further, by helping to ensure that NSCC collects margin amounts sufficient to manage NSCC's risks associated with municipal bonds, the proposed methodology would help limit NSCC's exposure in the event of a default of a member with positions in municipal bonds. Accordingly, the Commission believes that the proposed methodology would be consistent with promoting safety and soundness at NSCC.

Finally, as noted above, NSCC states that based on recent impact studies, while the proposed methodology would fully manage NSCC's applicable risks well above the 99% confidence level, it would reduce margin requirements for every NSCC member holding positions in municipal bonds.[38] The changes proposed in the Advance Notice would therefore result in lower capital demands on such members, who could benefit from having the ability to use their liquid resources for other purposes, including handling market stress events, which could, in turn, have beneficial implications for the stability of the broader financial system. Accordingly, the Division believes that the proposed methodology would be consistent with supporting the stability of the financial system and reducing systemic risks.

As described above in Section I.B., NSCC proposes to re-calibrate the municipal bond haircut percentages no less frequently than annually. Regular re-calibration of the municipal bond haircut percentages is necessary to ensure that the relevant calculations and resulting margin levels take into account any changes over time to the risk attributes of municipal bonds. The Commission believes that the proposal to re-calibrate the municipal bond haircut percentages no less frequently than annually would be consistent with robust risk management because it

[27] *Id.; See also* Securities Exchange Act Release No. 81485 (August 25, 2017), 82 FR 41433 (August 31, 2017) (File No. SR–NSCC–2017–008); Securities Exchange Act Release No. 84458 (October 19, 2018), 83 FR 53925 (October 25, 2018) (File No. SR–NSCC–2018–009).

[28] For example, the market price risk for issues of a municipality facing technical default following a natural disaster may not be fully captured by the proposed methodology due to the liquidity profile of municipal securities.

[29] *See* 12 U.S.C. 5461(b).

[30] 12 U.S.C. 5464(a)(2).

[31] 12 U.S.C. 5464(b).

[32] 12 U.S.C. 5464(c).

[33] 17 CFR 240.17Ad–22. *See* Securities Exchange Act Release No. 68080 (October 22, 2012), 77 FR 66220 (November 2, 2012) (S7–08–11). *See also* Securities Exchange Act Release No. 78961 (September 28, 2016), 81 FR 70786 (October 13, 2016) (S7–03–14) (''Covered Clearing Agency Standards''). The Commission established an effective date of December 12, 2016 and a compliance date of April 11, 2017 for the Covered Clearing Agency Standards. NSCC is a ''covered clearing agency'' as defined in Rule 17Ad–22(a)(5).

[34] 17 CFR 240.17Ad–22.

[35] 12 U.S.C. 5464(b).

[36] 17 CFR 240.17Ad–22(e)(4) and (e)(6).

[37] Notice of Filing, *supra* note 4 at 2199.

[38] *Id.;* Proposed Rule Change, *supra* note 4 at 154.

would require NSCC to regularly review the municipal bond haircut percentages to ensure that margin levels remain commensurate with the particular risk attributes of municipal bonds. Additionally, by helping to ensure that NSCC continues to collect margin amounts sufficient to manage the risks associated with municipal bonds, NSCC's proposal to re-calibrate the municipal bond haircut percentages no less frequently than annually would help limit NSCC's exposure in the event of a default of a member with positions in municipal bonds. Accordingly, the Commission believes that NSCC's proposal to re-calibrate the municipal bond haircut percentages no less frequently than annually would be consistent with promoting safety and soundness at NSCC, which in turn would support the stability of the broader financial system and reduce systemic risks.

As described above in Section I.B., a certain municipality or issuer may present unique risks to NSCC not otherwise captured by the proposed methodology's use of a percentage derived from the maximum of the applicable tenor-based index, municipal bond sector-based indices, and high-yield indices. In such scenarios, NSCC proposes to have the ability to use the highest percentage generated for any municipal bond group when calculating the haircut-based volatility component for municipal bonds issued by the municipality or issuer presenting such unique risks. The Commission believes the proposed discretion allowing NSCC to apply the highest percentage to municipal bonds issued by a municipality or issuer presenting unique risks would be consistent with robust risk management by helping to ensure that NSCC collects sufficient margin amounts with respect to such securities. Additionally, by helping to ensure that NSCC collects sufficient margin amounts with respect to municipal bonds issued by a municipality or issuer presenting such unique risks, the proposed discretion could help limit NSCC's exposure in the event of a default of a member with positions in such municipal bonds. Accordingly, the Commission believes that the proposed discretion allowing NSCC to apply the highest percentage to municipal bonds issued by a municipality or issuer presenting unique risks would be consistent with promoting safety and soundness at NSCC, which in turn would support the stability of the broader financial system and reduce systemic risks.

B. Consistency With Rule 17Ad–22(e)(4)(i)

Rule 17Ad–22(e)(4)(i) requires that NSCC establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by maintaining sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence.[39]

As described above in Section I.B., NSCC proposes to replace the current methodology for calculating municipal bond haircut percentages with a methodology that would utilize the historical returns of one or more benchmark indices over a look-back period of not shorter than 10 years, using a minimum 99% calibration percentile. These changes would result in more precisely determined margin amounts, while still managing NSCC's applicable risks well above the 99% confidence level.[40] Accordingly, the Commission believes that the proposed methodology is consistent with Rule 17Ad–22(e)(4)(i) because it should enable NSCC to effectively identify, measure, monitor, and manage its credit exposures to members with positions in municipal bonds, including by maintaining sufficient financial resources to cover NSCC's credit exposure to such members fully with a high degree of confidence.[41]

As described above in Section I.B., NSCC proposes to re-calibrate the municipal bond haircut percentages no less frequently than annually. The proposal would require NSCC to regularly review the municipal bond haircut percentages, thereby helping to ensure that the haircut percentages and resulting margin levels take into account any changes over time to the risk attributes of municipal bonds. Accordingly, the Commission believes that the proposal to re-calibrate the municipal bond haircut percentages no less frequently than annually is consistent with Rule 17Ad–22(e)(4)(i) because it should allow NSCC to effectively identify, measure, monitor, and manage its credit exposures to members with positions in municipal bonds, including by maintaining sufficient financial resources to cover NSCC's credit exposure to such members fully with a high degree of confidence.[42]

As described above in Section I.B., NSCC proposes to have the ability to use the highest percentage generated for any municipal bond group when calculating the haircut-based volatility component for municipal bonds issued by a municipality or issuer presenting unique risks not otherwise captured by the calculations in the proposed methodology. Such discretion should help ensure that NSCC collects sufficient margin amounts with respect to those securities. Accordingly, the Commission believes that the proposed ability to apply the highest percentage to such municipal bonds is consistent with Rule 17Ad–22(e)(4)(i) because it should better enable NSCC to effectively identify, measure, monitor, and manage its credit exposures to members with positions in such municipal bonds, including by maintaining sufficient financial resources to cover NSCC's credit exposure to such members fully with a high degree of confidence.[43]

C. Consistency With Rules 17Ad–22(e)(6)(i) and (v)

Rule 17Ad–22(e)(6)(i) requires that NSCC establish, implement, maintain and enforce written policies and procedures reasonably designed to cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market.[44] Rule 17Ad–22(e)(6)(v) requires that NSCC establish, implement, maintain and enforce written policies and procedures reasonably designed to cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, uses an appropriate method for measuring credit exposure that accounts for relevant product risk factors and portfolio effects across products.[45]

As described above in Section I.B., NSCC proposes to replace the current methodology for calculating municipal bond haircut percentages with a methodology that would utilize the historical returns of one or more benchmark indices over a look-back period of not shorter than 10 years, using a minimum 99% calibration percentile. NSCC designed the proposed methodology to generate margin amounts that are more commensurate with the risk attributes of municipal bonds than the current methodology. Accordingly, the Commission believes

[39] 17 CFR 240.17Ad–22(e)(4)(i).

[40] Notice of Filing, *supra* note 4 at 2199.

[41] *Id.*

[42] *Id.*

[43] *Id.*

[44] 17 CFR 240.17Ad–22(e)(6)(i).

[45] 17 CFR 240.17Ad–22(e)(6)(v).

that the proposed methodology is consistent with Rules 17Ad–22(e)(6)(i) and (v) because it is designed to establish a risk-based margin system that (1) considers and produces relevant margin levels commensurate with the risks and particular attributes of municipal bonds, and (2) uses an appropriate method for measuring credit exposure that accounts for municipal bond risk factors and portfolio effects.[46]

As described above in Section I.B., NSCC proposes to re-calibrate the municipal bond haircut percentages no less frequently than annually. The proposal would require NSCC to regularly review the municipal bond haircut percentages, thereby helping to ensure that the haircut percentages and resulting margin levels take into account any changes over time to the risk attributes of municipal bonds. Accordingly, the Commission believes that the proposal to re-calibrate the municipal bond haircut percentages no less frequently than annually is consistent with Rules 17Ad–22(e)(6)(i) and (v) because it would contribute to a risk-based margin system designed to (1) consider and produce relevant margin levels commensurate with the risks and particular attributes of municipal bonds, and (2) use an appropriate method for measuring credit exposure that accounts for municipal bond risk factors and portfolio effects.[47]

As described above in Section I.B., NSCC proposes to have the ability to use the highest percentage generated for any municipal bond group when calculating the haircut-based volatility component for municipal bonds issued by a municipality or issuer presenting unique risks not otherwise captured by the calculations in the proposed methodology. This discretion should help ensure that NSCC collects sufficient margin amounts with respect to those securities. Accordingly, the Commission believes that the proposed discretion to apply the highest percentage to such municipal bonds is consistent with Rules 17Ad–22(e)(6)(i) and (v) because it would contribute to a risk-based margin system designed to (1) consider and produce relevant margin levels commensurate with the risks and particular attributes of municipal bonds, and (2) use an appropriate method for measuring credit exposure that accounts for municipal bond risk factors and portfolio effects.[48]

[46] 17 CFR 240.17Ad–22(e)(6)(i) and (v).

[47] *Id.*

[48] 17 CFR 240.17Ad–22(e)(6)(i) and (v).

III. Conclusion

It is therefore noticed, pursuant to Section 806(e)(1)(I) of the Clearing Supervision Act, that the Commission *does not object* to Advance Notice (SR–NSCC–2019–801) and that NSCC is *authorized* to implement the proposed change as of the date of this notice or the date of an order by the Commission approving proposed rule change SR–NSCC–2019–004, whichever is later.

By the Commission.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–03055 Filed 2–14–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88165; File No. SR–NYSE–2020–08]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Price List

February 11, 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 January 31, 2020, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, 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 Price List to eliminate the Step Up Tier 2 Adding Credit. The Exchange proposes to implement the fee changes effective February 3, 2020. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and 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 Price List to eliminate the Step Up Tier 2 Adding Credit.

The proposed change responds to the current competitive environment where order flow providers have a choice of where to direct liquidity-providing orders by offering further incentives for member organizations to send additional displayed liquidity to the Exchange.

The Exchange proposes to implement the fee changes effective February 3, 2020.

Competitive Environment

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [4]

As the Commission itself recognized, the market for trading services in NMS stocks has become ''more fragmented and competitive.'' [5] Indeed, equity trading is currently dispersed across 13 exchanges,[6] 31 alternative trading

[4] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37495, 37499 (June 29, 2005) (S7–10–04) (Final Rule) (''Regulation NMS'').

[5] *See* Securities Exchange Act Release No. 51808, 84 FR 5202, 5253 (February 20, 2019) (File No. S7–05–18) (Transaction Fee Pilot for NMS Stocks Final Rule) (''Transaction Fee Pilot'').

[6] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/. See*

systems,[7] and numerous broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no single exchange has more than 18% market share (whether including or excluding auction volume).[8] Therefore, no exchange possesses significant pricing power in the execution of equity order flow. More specifically, the Exchange's market share of trading in Tapes A, B and C securities combined is less than 15%.

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can move order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. With respect to non-marketable order flow that would provide displayed liquidity on an Exchange, member organizations can choose from any one of the 13 currently operating registered exchanges to route such order flow. Accordingly, competitive forces constrain exchange transaction fees that relate to orders that would provide liquidity on an exchange.

In response to this competitive environment, the Exchange has established incentives for its member organizations who submit orders that provide liquidity on the Exchange. The proposed fee change is designed to eliminate a pricing tier intended to incentivize member organizations to step up their liquidity-providing orders on the Exchange on all tapes that has not encouraged member organizations to increase their activity on the Exchange.

Proposed Rule Change

Under the current Step Up Tier 2 Adding Credit, a member organization that sends orders, except Mid-Point Liquidity Orders (''MPL'') and Non-Displayed Limit Orders, that add liquidity (''Adding ADV'') in Tape A securities would receive a credit of $0.0029 if:

- The member organization quotes at least 15% of the National Best Bid or Offer (''NBBO'') in 300 or more Tape A securities on a monthly basis, and
- the member organization's Adding ADV as a percentage of NYSE consolidated average daily volume (''CADV''), excluding any orders by a Designated Market Maker (''DMM''), that is at least two times more than the member organization's July 2019 Adding ADV as a percentage of NYSE CADV, and
- the member organization's Adding ADV as a percentage of NYSE CADV, excluding any liquidity added by a DMM, exceeds that member organization's Adding ADV in July 2019 taken as a percentage of NYSE CADV by at least 1.05% of NYSE CADV over that Member Organization's July 2019 Adding ADV as a percentage of NYSE CADV.

In addition, a member organization that meets these requirements, and thus qualifies for the $0.0029 credit in Tape A securities, would be eligible to receive an additional $0.00005 per share if trades in Tapes B and C securities against the member organization's orders that add liquidity, excluding orders as a Supplemental Liquidity Provider (''SLP''), equal to at least 0.20% of Tape B and Tape C CADV combined.

The Exchange proposes to eliminate this tier in its entirety. Current Step Up Tier 3 Adding Credit would become the new Step Up Tier 2 Adding Credit. The requirements for qualifying for the current Step Up Tier 3 Adding Credit would remain unchanged.

The Exchange proposes eliminating the tier because it has not encouraged member organizations to increase their activity in order to qualify for the tier as significantly as the Exchange had anticipated. The Exchange does not know how much order flow member organizations choose to route to other exchanges or to off-exchange venues. The Exchange has nonetheless observed that, historically, few members have received this credit, with little associated volume, and it has not served to meaningfully increase activity on the Exchange or improve market quality. Indeed, no member organization currently qualifies for the credit. The Exchange therefore proposes to eliminate it.

The proposed change 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 fragmented and competitive market. 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 ever-shifting market share among the exchanges from month to month demonstrates that market participants can move order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. With respect to non-marketable orders which provide liquidity on an Exchange, member organizations can choose from any one of the 13 currently operating registered exchanges to route such order flow. Accordingly, competitive forces constrain exchange transaction fees that relate to orders that would provide displayed liquidity on an exchange. Stated otherwise, changes to exchange transaction fees can have a direct effect on the ability of an exchange to compete for order flow.

Given the competitive environment, the proposal to eliminate the Step Up Tier 2 Adding Credit is reasonable. Currently, no member organization qualifies for the credit. Member organizations have not increased their activity significantly as the Exchange anticipated they would in order to qualify for the credit, related volume is low, and it has not served to meaningfully increase volume or market quality.

The Proposal is an Equitable Allocation of Fees

The Exchange believes the proposal equitably allocates its fees among its market participants by fostering

generally https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html.

[7] *See* FINRA ATS Transparency Data, *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[8] *See* Cboe Global Markets U.S. Equities Market Volume Summary, *available at http://markets.cboe.com/us/equities/market_share/.*

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) & (5).

[11] *See* Regulation NMS, 70 FR at 37499.

liquidity provision and stability in the marketplace.

The Exchange believes that eliminating the step up tier constitutes an equitable allocation of fees because it would apply equally to all similarly situated member organizations that submit orders to the NYSE, and that all such member organizations would continue to be subject to the same fee structure, and access to the Exchange's market would continue to be offered on fair and nondiscriminatory terms. As noted, the credit has not prompted a meaningful increase in volume or market quality. No member organization currently qualifies for the credit, and no member organization would accordingly be affected by its elimination.

The Proposal Is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory. In the prevailing competitive environment, member organizations are free to disfavor the Exchange's pricing if they believe that alternatives offer them better value.

The proposal is not unfairly discriminatory because it neither targets nor will it have a disparate impact on any particular category of market participant. The proposal does not permit unfair discrimination because elimination of the tier would apply to all similarly situated member organizations and other market participants, who would all be eligible for the remaining step up credits on an equal basis. As noted, no member organization currently qualifies for the credit and thus no member organizations operating on the Exchange would be disadvantaged by its elimination. In addition, elimination of the credit would allow the Exchange to consider new, more effective incentives to attract order flow to the Exchange.

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 the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for member organizations. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [13]

Intramarket Competition. The Exchange believes that the proposed elimination of the step up credit will not place any undue burden on competition. The credit has not served its intended purpose of incentivizing a broader population of member organizations to increase their participation on the Exchange. Elimination of the credit would impact no member organizations because no member organization currently qualifies for it. Moreover, member organizations may seek to mitigate the effects of the loss of the credit by qualifying for the remaining step up credits the Exchange offers that would remain available to all market participants. Accordingly, 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 market in which market 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. As previously noted, the Exchange's market share of trading in Tapes A, B and C securities combined is under 15%. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and with off-exchange venues. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange does not believe its proposed fee change can impose any burden on intermarket competition. The Exchange's proposal to eliminate the step up tier credit will not meaningfully impact intermarket competition. As discussed above, no member organization currently qualifies for the credit. The Exchange also believes that the proposed change is designed to provide the public and investors with a Price List that is clear and consistent, thereby reducing burdens on the marketplace and facilitating investor protection.

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) [14] of the Act and subparagraph (f)(2) of Rule 19b–4 [15] 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) [16] 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–NYSE–2020–08 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2020–08. 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

[12] 15 U.S.C. 78f(b)(8).

[13] Regulation NMS, 70 FR at 37498–99.

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(2).

[16] 15 U.S.C. 78s(b)(2)(B).

only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2020–08 and should be submitted on or before March 10, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–03094 Filed 2–14–20; 8:45 am]

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[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88173; File No. SR–NASDAQ–2020–006]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Remove Listing Rule and Other Amendments

February 11, 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 January 29, 2020, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend The Nasdaq Options Market LLC (''NOM'') Rules at Options 1, Section 1 (Definitions), Options 2, Section 4 (Obligations of Market Makers), Section 5 (Market Maker Quotations), Options 3, Section 2 (Units of Trading and Meaning if Premium Quotes and Orders), Options 3, Section 3 (Minimum Increments), Options 3, Section 8 (Opening and Halt Cross), Options 3, Section 19 (Mass Cancellation of Trading Interest), Options 4, Section 5 (Series of Options Contracts Open for Trading), Options 4A, Section 2 (Definitions), Section 3 (Designation of a Broad-Based Index), Section 6 (Position Limits for Broad-Based Index Options), Section 11 (Trading Sessions), Section 12 (Terms of Index Options Contracts), Section 14 (Disclaimers), Options 5, Section 2 (Order Protection), Section 4 (Order Routing), Options 6C Exercises and Deliveries, and Options 7 (Pricing Schedule). The Exchange also proposes to relocate current rule text to new Options 2, Section 6 entitled ''Market Maker Orders'' and reserve certain rules within the Rulebook. The text of the proposed rule change is available on the Exchange's website at *http://nasdaq.cchwallstreet.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 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 NOM's Rules at Options 1, Section 1 (Definitions), Options 2, Section 4 (Obligations of Market Makers), Section 5 (Market Maker Quotations), Options 3, Section 2 (Units of Trading and Meaning if Premium Quotes and Orders), Options 3, Section 3 (Minimum Increments), Options 3, Section 8 (Opening and Halt Cross), Options 3, Section 19 (Mass Cancellation of Trading Interest), Options 4, Section 5 (Series of Options Contracts Open for Trading), Options 4A, Section 2 (Definitions), Section 3 (Designation of a Broad-Based Index), Section 6 (Position Limits for Broad-Based Index Options), Section 11 (Trading Sessions), Section 12 (Terms of Index Options Contracts), Section 14 (Disclaimers), Options 5, Section 2 (Order Protection), Section 4 (Order Routing), Options 6C Exercises and Deliveries, and Options 7 (Pricing Schedule). The Exchange also proposes to relocate current rule text to new Options 2, Section 6 entitled ''Market Maker Orders'' and reserve certain rules within the Rulebook. Each change is described below.

Rulebook Harmonization

The Exchange recently harmonized its Rulebook in connection with other Nasdaq affiliated markets. The Exchange proposes to reserve certain rules within the Nasdaq Rulebook to represent the presence of rules in similar locations in other Nasdaq affiliated Rulebooks (*e.g.,* Nasdaq Phlx LLC).[3]

The Exchange proposes to reserve Sections 17–22 within General 2, Organization and Administration. The Exchange proposes to reserve Sections 11–14 within Options 2, Options Market Participants. The Exchange proposes to reserve Sections 17–21 within Options 4A, Options Index Rules. The Exchange proposes to reserve new section Options 4B. The Exchange proposes to reserve Sections 8–13 within Options 6, Options Trade Administration. The Exchange proposes to reserve Section 7 within Options 6C, which is currently titled ''Exercises and Deliveries.'' The Exchange proposes to retitle Options 6C as ''Margins'' to harmonize the title to the other Nasdaq affiliated markets. The Exchange proposes to reserve Section 24 within Options 9, Business Conduct.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* SR–Phlx–2020–03 (not yet published).

Definitions

The Exchange proposes to add the definition of an ''Away Best Bid or Offer'' or ''ABBO'' within Options 1, Section 1(a)(1). This term is utilized throughout the Rulebook. Defining this term will bring greater transparency to the Rulebook. The Exchange proposes to renumber the remaining definitions and also update corresponding cross-references within Options 7, Section 1.

The Exchange proposes to remove the definitions of ''class of options'' and ''series of options'' as they are duplicative of the definitions for ''class'' and ''series.'' The Exchange proposes to remove the terms ''System Book Feed'' and ''System Securities'' from the Options 1, Section 1. The term ''System Book Feed'' is not utilized in the Rulebook currently. The term ''System Securities'' is only utilized within the definition of the term ''System'' at current Options 1, Section 1(a)(60) and within Options 3, Section 8, Opening and Halt Cross.'' The term is simply replaced by referring to option series. The Exchange believes that replacing the term with the term ''option series'' will make the Rulebook clear.

Finally, the Exchange is removing the phrase '', or the United States dollar'' from the definition of ''foreign currency'' within current Options 1, Section 1(a)(20). This reference is not needed in this string cite because the United States dollar is a medium of exchange as noted in the introductory phrase to the string cite.

Relocation of Options 2 Rules

The Exchange proposes to relocate Options 2, Section 4(d) and Section 5(e) to Options 2, Section 6, which is currently reserved. Specifically, the Exchange proposes to relocate these sections into Options 6(a) and (b), respectively. Proposed Options 2, Section 6 would be titled ''Market Maker Orders.'' This relocation will harmonize the location of these rule to other Nasdaq affiliated markets.

Removal of Various Listings

Mini Options

The Exchange has not listed Mini Options in several years and is proposing to delete its listing rules and other ancillary trading rules related to the listing of Mini Options. The Exchange notes that it has no open interest in Mini Options.

Specifically, the Exchange proposes to amend Options 3, Section 2 (Units of Trading and Meaning of Premium Quotes and Orders), Options 3, Section 3 (Minimum Increments) and Options 4, Section 5 (Series of Options Contracts Open for Trading) at Supplementary Material .15) to remove references to the handling of Mini Options in the System. The Exchange also proposes to remove pricing for Mini Options within Options 7, Section 2 (Nasdaq Options Market—Fees and Rebates). The Exchange is also amending Supplementary Material .01 to Options 4A, Section 2.

In the event that the Exchange desires to list Mini Options in the future, it would file a rule change with the Commission to adopt rules to list Mini Options.

U.S. Dollar-Settled Foreign Currency Options

The Exchange has not listed U.S. Dollar-Settled Foreign Currency Options (''FCOs'') in several years and is proposing to delete its listing rules and other ancillary trading rules related to the listing of FCOs. The Exchange notes that it has no open interest in FCOs.

Specifically, the Exchange proposes to amend Supplementary Material .16 to Options 4, Section 5 (Series of Options Contracts Open for Trading) to remove references to the handling of FCOs in the System.

In the event that the Exchange desires to list FCOs in the future, it would file a rule change with the Commission to adopt rules to list FCOs.

Mini-Nasdaq-100 Index

The Exchange has not listed Mini-Nasdaq-100 Index options or ''MNX'' or ''Mini-NDX'' in several years and is proposing to delete its listing rules and other ancillary trading rules related to the listing of Mini-Nasdaq-100 Index options. The Exchange notes that it has no open interest in Mini-Nasdaq-100 Index options.

Specifically, the Exchange proposes to amend Supplementary Material .05 to Options 4, Section 5 (Series of Options Contracts Open for Trading) and Options 4A, Section 12 (Terms of Index Options Contracts) to remove references to the handling of Mini-Nasdaq-100 Index options in the System.

In the event that the Exchange desires to list Mini-Nasdaq-100 Index options in the future, it would file a rule change with the Commission to adopt rules to list Mini-Nasdaq-100 Index options.

MSCI EM Index and MSCI EAFE Index

The Exchange has not listed the MSCI EM Index or MSCI EAFE Index in several years and is proposing to delete its listing rules and other ancillary trading rules related to the listing of the MSCI EM Index and MSCI EAFE Index. The Exchange notes that it has no open interest in the MSCI EM Index and MSCI EAFE Index.

Specifically, the Exchange proposes to amend Supplementary Material .01 to Options 4A, Section 2 (Definitions), Section 3 (Designation of a Broad-Based Index), Section 6 (Position Limits for Broad-Based Index Options), Section 11(Trading Sessions) Section 12 (Terms of Index Options Contracts), Section 14 (Disclaimers) to remove references to the handling of the MSCI EM Index and MSCI EAFE Index in the System.

The Exchange proposes to add rule text within Options 4A, Section 12(a)(6) which indicates, ''There are currently no P.M.-settled index options approved for trading on NOM.''

In the event that the Exchange desires to list the MSCI EM Index and/or MSCI EAFE Index in the future, it would file a rule change with the Commission to adopt rules to list the MSCI EM Index and/or MSCI EAFE Index.

Minimum Increments

The Exchange proposes to amend Options 3, Section 3 to relocate Section 3(a)(3) into a new Supplementary Material .01 and title the section, ''Penny Pilot Program.'' The Exchange also proposes to amend a typographical error in Options 3, Section 3(a)(3) to replace ''QQQQs'' with ''QQQs.'' The other changes relate to the removal of Mini Options as explained herein.

Mass Cancellation of Trading Interest

The Exchange proposes to amend the description of Options 3, Section 19 titled ''Mass Cancellation of Trading Interest.'' The proposed amended rule would state, '' An Options Participant may cancel any bids, offers, and orders in any series of options by requesting NOM Market Operations [4] staff to effect such cancellation as per the instructions of the Options Participant.'' The Exchange is not amending the System with respect to this rule change. The proposed amended language merely makes clear that an Options Participant may contact NOM Market Operations and request the Exchange to cancel any bid, offer or order in any series of options. This is a voluntary service that is offered to market participants. The Exchange, would cancel such bid, offer or order pursuant to the Member's instruction. This proposed new rule would conform to rules of other Nasdaq affiliated markets.[5]

[4] The request to Market Operations is a manual request which is made telephonically.

[5] *See* Nasdaq Phlx LLC (''Phlx''), Nasdaq ISE, LLC (''ISE''), Nasdaq GEMX, LLC (''GEMX'') and Nasdaq MRX, LLC (''MRX'') Options 3, Section 19.

Order Routing

Phlx recently amended Options 5, Section 4.[6] The Exchange proposes to make similar amendments to the NOM Rule. The amendments clarity and correct the rule text to represent current System functionality. Currently, Options 5, Section 4(a)(iii)(A), relating to DNR Orders, states,

> Any incoming order interacting with such a resting DNR Order will execute at the ABBO price, unless (1) the ABBO is improved to a price which crosses the DNR displayed price, in which case the incoming order will execute at the previous ABBO price; (2) the ABBO is improved to a price which locks the DNR's displayed price, in which case the incoming order will execute at the DNR's displayed price. Should the best away market move to an inferior price level, the DNR Order will automatically re-price from its one MPV inferior to the original away best bid/offer price to one MPV away from the new away best bid/offer price or its original limit price.

The Exchange proposes to make non-substantive amendments to this rule text within Options 5, Section 4(a)(iii)(A), relating to DNR Orders, to align the rule text with Phlx Rule 1093. The Exchange proposes to instead provide:

> Any incoming order interacting with such a resting DNR Order will execute at the ABBO price, unless (1) the ABBO is improved to a price which crosses the DNR Order's already displayed price, in which case the incoming order will execute at the previous ABBO price as the away market crossed a displayed price; or (2) the ABBO is improved to a price which locks the DNR Order's displayed price, in which case the incoming order will execute at the DNR Order's displayed price. Should the best away market move to an inferior price level, the DNR Order will automatically re-price from its one MPV inferior to the original ABBO and display one MPV away from the new ABBO or its original limit price.

This proposed new text intends to make clear that if the Exchange's System is executing an incoming order against a resting DNR Order which is displayed, it would not consider an updated ABBO which crossed the displayed DNR Order. The System would not take into account the away market order or quote which crossed the DNR Order's displayed price. The Exchange is not trading-through an away market in this scenario, rather an away market is crossing NOM's displayed market and therefore that market has the obligation not to trade-through NOM's displayed price. A similar change is being made to the last sentence of Options 5, Section 4(a)(iii)(B)(4) for SEEK Orders and the last sentence Options 5, Section 4(a)(iii)(C)(4) for SRCH Orders. By way of example, consider the following sequence of events in the System:

9:45:00:00:00—MIAX Quote 0.95 × 1.20
9:45:00:00:10—OPRA updates MIAX BBO 0.95 × 1.20
9:45:00:00:20—NOM Local BBO Quote 1.00 × 1.15
9:45:00:00:30—OPRA disseminates NOM BBO updates: 1.00 × 1.15
9:45:00:00:35: CBOE Quote 1.00 × 1.12
9:45:00:00:45—OPRA disseminates CBOE BBO 1.00 × 1.12
9:45:00:00:50—DNR Order: Buy 5 @1.15 (exposes @ABBO of 1.12, displays 1 MPV from ABBO @1.11)
9:45:00:00:51—OPRA disseminates NOM BBO updates: 1.11 × 1.15 (1.11 being the DNR Order displaying 1 MPV from ABBO)
9:45:00:00:60—MIAX Quote updates to 1.00 × 1.10 (1.10 crosses the displayed DNR Order price, violating locked/crossed market rules; henceforth, we need not protect this price)
9:45:00:00:65—OPRA disseminates MIAX BBO 1.00 × 1.10
9:45:00:00:75—NOM Market Maker Order to Sell 5 @1.09
9:45:00:00:76—Market Maker Order immediately executes against DNR Order 5 contracts @1.12 (1.12 being the 'previous' ABBO price disseminated by CBOE before the receipt of the DNR Order that was subsequently and illegally crossed by MIAX's 2nd quote)
9:45:00:00:77—OPRA disseminates NOM BBO updates: 1.10 × 1.15 (reverts back to BBO set by NOM Local Quote since the DNR Order has executed)

The remainder of the changes to Options 5, Section 4(a)(iii)(A) are non-substantive changes designed to bring clarity to the rule text. By way of example, the Exchange proposes to add the word ''Order'' after ''DNR,'' change the words ''away best bid/offer price'' to the acronym ''ABBO'' and add the words ''display'' and ''already'' to the rule text to make clear that the intent of the sentence.

The Exchange proposes to amend Options 5, Section 4(a)(iii)(B)(4) to amend the sentence which provides, ''If there exists a locked ABBO when the SEEK Order is entered onto the Order Book, the SEEK Order will display at the locked ABBO price.'' The Exchange is amending this sentence to provide, ''If there exists a locked ABBO when the SEEK Order is entered onto the Order Book, the SEEK Order will be entered at the ABBO price and displayed one MPV inferior to the ABBO.'' This is true of both SEEK and SRCH Orders. Where there exists a locked ABBO when the SEEK Order or SRCH Order is entered onto the Order Book, the SEEK Order or SRCH Order will be entered into the Order Book at the ABBO price and displayed one MPV inferior to the ABBO. The Exchange is proposing to add additional rule text to Options 5, Section 4(a)(iii)(B)(4). This amendment corrects the current rule text.

The Exchange also proposes to remove the sentence, ''When checking the Order Book, the System will seek to execute at the price at which it would send the order to an away market.'' The Exchange proposes to remove this sentence because the price at which the order would route in explained in greater detail within Options 5, Section 4(a)(iii)(B)(4). Also, this sentence is confusing because the price at which an order would execute is dependent on the scenario within which an order would route. Removing this sentence will remove any confusion related to the price at which the order would route. The Exchange also proposes to remove the same sentence concerning SRCH Orders within Options 5, Section 4(a)(iii)(C)(4).

Other Amendments

The Exchange proposes to correct the lettering within General 9, Section 1, General Standards. The Exchange proposes to correct a typographical error within Options 4A, Section 12. Specifically, the reference to Options 4, Section 6 should have referenced Options 4, Section 5 instead. The Exchange proposes to remove a reference to paragraph (c) within Options 5, Section 2, as there is no paragraph (c) within the Rule. The Exchange also proposes to update rulebook citations within Options 7, Pricing Schedule to reflect the proposed changes to Options 1, Section 1 (Definitions).

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

[6] *See* Securities Exchange Act Release No. 87811 (December 20, 2019), 84 FR 72017 (December 30, 2019) (SR–Phlx–2019–56).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

Rulebook Harmonization

The Exchange's proposal to reserve various sections of the Rules in order to harmonize its Rulebook with other Nasdaq affiliated markets is not a substantive amendment.

Definitions

The Exchange's proposal to add the definition of an ''Away Best Bid or Offer'' or ''ABBO'' within Options 1, Section 1(a)(1) is consistent with the Act because these amendments will add transparency to the Rulebook. The Exchange's proposal to remove the terms ''class of options,'' ''series of options,'' ''System Book Feed'' and ''System Securities'' from the Options 1, Section 1 is also consistent with the Act. The term ''System Book Feed'' is not utilized in the Rulebook currently and therefore this term does not need to be defined. The term ''System Securities'' is only utilized within the definition of the term ''System'' at current Options 1, Section 1(a)(60) and within Options 3, Section 8, Opening and Halt Cross.'' Replacing the term with the term ''option series'' will make the Rulebook clear.

Relocation of Options 2 Rules

The proposal to relocate Options 2, Section 4(d) and Section 5(e) to Section 6 into Options 6(a) and (b), respectively is consistent with the Act. This amendment is not substantive.

Removal of Various Listings

Mini Options

The Exchange's proposal to removal references to the listing and handling of Mini Options is consistent with the Act because Mini Options have not been listed in several years. Also, the Exchange notes that it has no open interest in Mini Options. In the event that the Exchange desires to list Mini Options in the future, it would file a rule change with the Commission to adopt rules to list Mini Options.

U.S. Dollar-Settled Foreign Currency Options

The Exchange's proposal to removal references to the listing and handling of FCOs is consistent with the Act because FCOs have not been listed in several years. Also, the Exchange notes that it has no open interest in FCOs. In the event that the Exchange desires to list FCOs in the future, it would file a rule change with the Commission to adopt rules to list FCOs.

Mini-Nasdaq-100 Index

The Exchange's proposal to removal references to the listing and handling Mini-Nasdaq-100 Index options is consistent with the Act because Mini-Nasdaq-100 Index options have not been listed in several years. Also, the Exchange notes that it has no open interest in Mini-Nasdaq-100 Index options. In the event that the Exchange desires to list Mini-Nasdaq-100 Index options in the future, it would file a rule change with the Commission to adopt rules to list Mini-Nasdaq-100 Index options.

MSCI EM Index and MSCI EAFE Index

The Exchange's proposal to removal references to the listing and handling of MSCI EM Index and MSCI EAFE Index options is consistent with the Act because MSCI EM Index and MSCI EAFE Index options have not been listed in several years. Also, the Exchange notes that it has no open interest in MSCI EM Index and MSCI EAFE Index options. In the event that the Exchange desires to list MSCI EM Index and MSCI EAFE Index options in the future, it would file a rule change with the Commission to adopt rules to list MSCI EM Index and MSCI EAFE Index options.

Minimum Increments

The Exchange's proposal to relocate parts of Options 3, Section 3 into a new Supplementary Material .01 and add a title for the Penny Pilot Program is consistent with the Act. This amendment will bring greater transparency to the Exchange's Rules.

Mass Cancellation of Trading Interest

The Exchange's proposal to amend the rule text of Mass Cancellation of Trading Interest rule within Options 3, Section 19 is consistent with the Act because the Exchange desires to conform the rule text to other Nasdaq affiliated markets.[9] Permitting Participants to contact Market Operations as a manual alternative to automated functionality, which similarly allows Participants to cancel interest, provides Participants experiencing their own system issues with a means to manage risk. Today, Participants are able to cancel interest, in an automated fashion through protocols [10] and the Kill Switch.[11] This is a voluntary services offered to all Participants.

This amended rule reflects the Exchange's current practice of allowing Participants to contact NOM Market Operations and request the Exchange to cancel any bid, offer or order in any series of options. The Exchange would continue to permit Participants to contact market operations and manually request cancellation of interest. The proposed amended language will make clear that an Options Participant may contact NOM Market Operations and request the Exchange to cancel any bid, offer or order in any series of options. The Exchange would continue to cancel such bid, offer or order pursuant to the Participant's instruction.

This service, which permits Participants to cancel interest, does not diminish a Market Maker's obligation with respect to providing two-sided quotations and this rule is not inconsistent with other firm quote obligations of the Market Maker. Upon the request of a Participant, NOM Market Operations will continue to manually input a mass cancellation message into the System consistent with the Participant's instruction to cancel trading interest. Once the mass cancellation message is entered into the System by NOM Market Operations, the message will be accepted by the System in the order of receipt in the queue such that the interest that was already accepted into the System will be processed prior to the mass cancellation message. In addition, mass cancellation messages entered into the System by NOM Market Operations are handled by the System through the same queuing mechanism that a quote or order message is handled by the System. The Exchange notes its processing of a mass cancellation message inputted by NOM Market Operations and handled by the System is consistent with firm quote and order handling rules.

Order Routing

The Exchange's proposal to amend the sentence within Options 5, Section 4(a)(iii)(A) related to DNR Orders is consistent with the Act. The Exchange proposes to amend this rule text to clarify the current rule text. Specifically, the Exchange proposes to state, ''Any incoming order interacting with such a resting DNR Order will execute at the ABBO price, unless (1) the ABBO is improved to a price which crosses the DNR Order's already displayed price, in which case the incoming order will execute at the previous ABBO price as the away market crossed a displayed price; or (2) the ABBO is improved to a price which locks the DNR Order's displayed price, in which case the incoming order will execute at the DNR Order's displayed price.'' The System would not take into account the away market order or quote which crossed the DNR's displayed price. The Exchange is

[9] *See* note 5 above.

[10] *See* Options 3 at Supplementary Material .03 to Section 7.

[11] *See* Options 3, Section 17.

not trading-through an away market in this scenario, rather an away market is crossing NOM's displayed market and therefore that market has the obligation not to trade-through NOMs displayed price. Similar amendments were made to Options 5, Section 4(a)(iii)(B)(4) and Section 4(a)(iii)(C)(4). The remainder of the changes to this paragraph are clarifying non-substantive amendments.

The Exchange's proposal to remove the following sentence from Options 5, Section 4(a)(iii)(B)(4) and Section 4(a)(iii)(C)(4), ''When checking the Order Book, the System will seek to execute at the price at which it would send the order to an away market,'' is consistent with the Act because this sentence is vague. The price at which an order would execute is dependent on the scenario within which an order would route. Removing this sentence will remove any confusion related to the price at which the order would route. The proposed rule would also add additional detail about the scenarios under which an order would route away.

With respect to SEEK Orders within Options 5, Section 4(a)(iii)(B) as well as SRCH Orders within Options 5, Section 4(a)(iii)(C) the amendments are consistent with the Act as they protect investors and the general public by amending current incorrect rule text. If there exists a locked ABBO when the SEEK Order or SRCH Order is entered onto the Order Book, the SEEK Order or SRCH Order will be entered at the ABBO price and displayed one MPV inferior to the ABBO. The amendments to Options 5, Section 4 represent current System functionality. This new rule text will provide Participants with clarity as to the manner in which the System handles locked market conditions during routing. The proposed rule text is similar to rule text within Phlx Rule 1093.

Other Amendments

The Exchange's proposal to correct certain typographical errors and update rulebook citations are not substantive.

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.

Rulebook Harmonization

The Exchange's proposal to reserve various rules in connection with a larger Rulebook harmonization do not impose an undue burden on competition because these amendments are non-substantive.

Definitions

The Exchange's proposal to add the definition of an ''Away Best Bid or Offer'' or ''ABBO'' within Options 1, Section 1(a)(1) and remove the terms ''class of options,'' ''series of options,'' ''System Book Feed'' and ''System Securities'' from the Options 1, Section 1 do not impose an undue burden on competition because these amendments will add transparency to the Rulebook.

Relocation of Options 2 Rules

The proposal to relocate Options 2, Section 4(d) and Section 5(e) to Section 6, into Options 6(a) and (b) does not burden competition as this amendment is not substantive.

Removal of Various Listings

Mini Options

The Exchange's proposal to removal references to the listing and handling of Mini Options do not impose an undue burden on competition. Mini Options have not been listed in several years. Also, the Exchange notes that it has no open interest in Mini Options.

U.S. Dollar-Settled Foreign Currency Options

The Exchange's proposal to remove references to the listing of U.S. Dollar-Settled Foreign Currency Options (''FCOs'') does not impose an undue burden on competition. FCOs have not been listed in several years. The Exchange notes that it has no open interest in FCOs.

Mini-Nasdaq-100 Index

The Exchange's proposal to removal references to the listing and handling of Mini-Nasdaq-100 Index options does not impose an undue burden on competition. Mini-Nasdaq-100 Index options have not been listed in several years. Also, the Exchange notes that it has no open interest in Mini-Nasdaq-100 Index options.

MSCI EM Index and MSCI EAFE Index

The Exchange's proposal to removal references to the listing and handling of MSCI EM Index and the MSCI EAFE Index does not impose an undue burden on competition. Neither the MSCI EM Index nor the MSCI EAFE Index have been listed in several years. Also, the Exchange notes that it has no open interest in either the MSCI EM Index or the MSCI EAFE.

Minimum Increments

The Exchange's proposal to relocate parts of Options 3, Section 3 into a new Supplementary Material .01 and add a title for the Penny Pilot Program do not impose an undue burden on competition as these amendments are non-substantive.

Mass Cancellation of Trading Interest

The Exchange's proposal to amend the rule text of the Mass Cancellation of Trading Interest rule within Options 3, Section 19 does not impose an undue burden on competition because there is no corresponding change to the manner in which this service will be offered. It will continue to be offered to all Participants.

Order Routing

The Exchange believes that adding greater detail to its rules concerning routing of orders does not impose an undue burden on competition, rather it provides greater transparency as to the potential outcomes when utilizing different routing strategies. Further, the Exchange notes that market participants may elect not to route their orders. The Exchange continues to offer various options to its market participants with respect to routing.

Other Amendments

The Exchange proposes to correct typographical error and update rulebook citations do not impose and undue burden on competition as these amendments are non-substantive.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [12] and subparagraph (f)(6) of Rule 19b–4 thereunder.[13]

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as

Continued

A proposed rule change filed under Rule 19b–4(f)(6) [14] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[15] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requests that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange believes that adoption the term ''ABBO,'' would add greater transparency to its rules, and that removing the rule text related to various options listing which are no longer listed on the Exchange will provide Participants with notice of the unavailability of these listing. The Exchange also states that its amendment to its routing rules protects investors and the general public by providing clarity concerning the current operation of its System. The Exchange believes that the amended rules will provide market participants with greater information for each potential order routing strategy and, in general, provide greater transparency. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission waives the 30-day operative delay and designates the proposed rule change operative upon filing.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2020–006 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2020–006. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2020–006 and should be submitted on or beforeMarch 10, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–03100 Filed 2–14–20; 8:45 am]

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designated by the Commission. The Exchange has satisfied this requirement.

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

[16] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 11030]

Defense Trade Advisory Group; Notice of Membership

The U.S. Department of State's Bureau of Political-Military Affairs is accepting membership applications for the Defense Trade Advisory Group (DTAG). The Bureau of Political-Military Affairs is interested in applications from subject matter experts from the United States defense industry, relevant trade and labor associations, or academic and foundation personnel.

The DTAG was established as an advisory committee under the authority of 22 U.S.C. 2656 and the Federal Advisory Committee Act, 5 U.S.C. App. (''FACA''). The purpose of the DTAG is to provide the Bureau of Political-Military Affairs with a formal channel for regular consultation and coordination with U.S. private sector defense exporters and defense trade organizations on issues involving U.S. laws, policies, and regulations for munitions exports. The DTAG advises the Bureau on its support for and regulation of defense trade to help ensure that impediments to legitimate exports are reduced while the foreign policy and national security interests of the United States continue to be protected and advanced in accordance with the Arms Export Control Act (AECA), as amended. Major topics addressed by the DTAG include (a) policy issues on commercial defense trade and technology transfer; (b) regulatory and licensing procedures applicable to defense articles, services, and technical data; (c) technical issues involving the U.S. Munitions List (USML); and (d) questions related to the implementation of the AECA and International Traffic in Arms Regulations (ITAR).

Members are appointed by the Assistant Secretary of State for Political-Military Affairs on the basis of individual qualifications and technical expertise. Past members include representatives of United States defense industry, relevant trade and labor associations, or academic and foundation personnel. In accordance with the DTAG Charter, all DTAG members must be U.S. citizens. DTAG members are expected to represent the views of their organizations, while also demonstrating awareness of Department's mission of ensuring that commercial exports of defense articles and defense services advance U.S. national security and foreign policy objectives. In addition, DTAG members are expected to understand complex

issues related to commercial defense trade and industrial competitiveness and are expected to advise the Bureau on these matters.

DTAG members' responsibilities include:

- Serving a consecutive two-year term, which may be renewed or terminated at the discretion of the Assistant Secretary of State for Political-Military Affairs.
- Making recommendations in accordance with the DTAG Charter and the FACA.
- Making policy and technical recommendations within the scope of the U.S. commercial export control regime as set forth in the AECA, the ITAR, and appropriate directives.

Please note that DTAG members may not be reimbursed for travel, per diem, and other expenses incurred in connection with their duties as DTAG members. How to apply: Applications in response to this notice must contain the following information: (1) Name of applicant; (2) affirmation of U.S. citizenship; (3) organizational affiliation and title, as appropriate; (4) mailing address; (5) work telephone number; (6) email address; (7) resume; and (8) summary of qualifications for DTAG membership.

This information may be provided via two methods:

- Emailed to the following address: *DTAG@State.Gov.* In the subject field, please write, ''*DTAG Membership Application.*''
- Send in hardcopy to the following address: Barbara Eisenbeiss, PM/DDTC, SA–1, 12th Floor, Directorate of Defense Trade Controls, Bureau of Political Military Affairs, U.S. Department of State, Washington, DC 20522–0112. If sent via regular mail, we recommend you call Ms. Eisenbeiss (202–663–2835) to confirm she has received your package.

All applications must be postmarked by March 2, 2020.

Neal F. Kringel,

Alternate Designated Federal Officer, Defense Trade Advisory Group, Department of State.

[FR Doc. 2020–02797 Filed 2–14–20; 8:45 am]

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DEPARTMENT OF STATE

[Public Notice: 11032]

Notice of Public Meeting for International Maritime Organization Sub-Committee Meeting

The Department of State will conduct a public meeting at 10:00 a.m. on February 24, 2020, in Room 7K15–01 of the Douglas A. Munro Coast Guard Headquarters Building at St. Elizabeth's, 2703 Martin Luther King Jr. Avenue SE, Washington, DC 20593. The primary purpose of the meeting is to prepare for the seventh session of the International Maritime Organization's (IMO) Sub-Committee on Ship Systems and Equipment to be held at the IMO Headquarters, United Kingdom, March 2–6, 2020.

The agenda items to be considered include:

—Adoption of the Agenda
—Decisions of other IMO bodies
—New requirements for ventilation of survival craft
—Consequential work related to the new Code for ships operating in polar waters
—Revision of SOLAS chapter III and the LSA Code
—Review SOLAS chapter II–2 and associated codes to minimize the incidence and consequences of fires on ro-ro spaces and special category spaces of new and existing ro-ro passenger ships
—Amendments to MSC.1/Circ.1315
—Amendments to chapter 9 of the FSS Code for fault isolation requirements for cargo ships and passenger ship cabin balconies fitted with individually identifiable fire detector systems
—Requirements for onboard lifting appliances and anchor handling winches
—Safety objectives and functional requirements of the Guidelines on alternative design and arrangements for SOLAS chapters II–1 and III
—Development of guidelines for cold ironing of ships and consideration of amendments to SOLAS chapters II–1 and II–2
—Amendments to paragraph 4.4.7.6.17 of the LSA Code concerning single fall and hook systems with on-load release capability
—Revision of the Standardized Life-Saving Appliance Evaluation and Test Report Forms (MSC/Circ.980 and addenda)
—Revision of the Code of safety for diving systems (resolution A.831(19)) and the Guidelines and specifications for hyperbaric evacuation systems (resolution A.692(17))
—Amendments to SOLAS chapter III, LSA Code and resolution MSC.81(70) to remove the applicability of the requirements to launch free-fall lifeboats with the ship making headway at speeds up to 5 knots in calm water
—Unified interpretation of provisions of IMO safety, security and environment-related conventions
—Revision of the Guidelines for the maintenance and inspections of fixed carbon dioxide fire-extinguishing systems (MSC.1/Circ.1318)
—Biennial status report and provisional agenda for SSE 8
—Election of Chair and Vice-Chair for 2021
—Any other business

Members of the public may attend this meeting up to the seating capacity of the room. Upon request to the meeting coordinator, members of the public may also participate via teleconference, up to the capacity of the teleconference phone line. To facilitate the building security process, receive the call-in information, and to request reasonable accommodation, those who plan to attend should contact the meeting coordinator, LT Brock Hashimoto, by email at *Brock.J.Hashimoto@uscg.mil,* by phone at (202) 372–1426, or in writing at 2703 Martin Luther King Jr. Ave. SE, Stop 7509, Washington, DC 20593–7509 not later than February 14, 2020, 7 business days prior to the meeting. Requests made after February 14, 2020 might not be able to be accommodated. Please note that due to security considerations, two valid, government issued photo identifications must be presented to gain entrance to the Coast Guard Headquarters building. It is recommended that attendees arrive no later than 30 minutes ahead of the scheduled meeting for the security screening process. The Headquarters building is accessible by taxi, public transportation, and privately owned conveyance (upon request). In the case of inclement weather where the U.S. Government is closed or delayed, a public meeting may be conducted virtually. The meeting coordinator will confirm whether the virtual public meeting will be utilized and notify registered guests accordingly. Members of the public can find out whether the U.S. Government is delayed or closed by visiting *www.opm.gov/status/.*

Jeremy M. Greenwood,

Coast Guard Liaison Officer, Office of Ocean and Polar Affairs, Department of State.

[FR Doc. 2020–03109 Filed 2–14–20; 8:45 am]

BILLING CODE 4710–09–P

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meeting Notice; Unified Carrier Registration Plan Board Subcommittee Meeting

TIME AND DATE: February 20, 2020, from Noon to 3:00 p.m., Eastern time.

PLACE: This meeting will be accessible via conference call. Any interested person may call 1–866–210–1669,

passcode 5253902#, to listen and participate in this meeting.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Education and Training Subcommittee (the ''Subcommittee'') will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

Proposed Agenda

I. Call to Order—Subcommittee Chair

The Subcommittee Chair will welcome attendees, call the meeting to order, call roll for the Subcommittee, confirm whether a quorum is present, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—Executive Director

The UCR Executive Director will verify the publication of the meeting notice on the UCR website and in the **Federal Register**.

III. Review and Approval of Subcommittee Agenda and Setting of Ground Rules—Subcommittee Chair

For Discussion and Possible Subcommittee Action

The Subcommittee Agenda will be reviewed and the Subcommittee will consider adoption.

Ground Rules

➢ Subcommittee action only to be taken in designated areas on agenda.

➢ Please MUTE your phone.

➢ Please do not place the call on HOLD.

IV. Approval of Minutes from January 27, 2020 Meeting—UCR Operations Manager

• Draft minutes from the January 27, 2020 Education and Training Subcommittee meeting in San Antonio, Texas will be reviewed. The Subcommittee will consider action to approve.

V. Proposal for Education Modules—UCR Technology Director

The UCR Technology Director will review a proposal to develop each of the three education modules (Enforcement, UCR 101, and National Registration System), including format and budget. The Subcommittee will discuss and may take action to adopt the proposal within the allotted Fiscal Year 2020 budget for the UCR education program.

VI. Role of Subcommittee in Development of Modules—UCR Technology Director

The UCR Technology Director will lead a discussion on the need for assistance and guidance from the Subcommittee in the development of the modules.

VII. Planning for Education and Training Sessions at NCSTS Summer Meeting—Subcommittee Chair

The Subcommittee Chair will lead a discussion on the logistics and planning involved in the live education and training sessions to be held on June 9, 2020 in Portland, Oregon.

VIII. Other Items—Subcommittee Chair

The Subcommittee Chair will call for any other items the Subcommittee members would like to discuss.

IX. Adjourn—Subcommittee Chair

Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern time, February 12, 2020 at: *https://plan.ucr.gov.*

CONTACT PERSON FOR MORE INFORMATION: Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305–3783, *eleaman@board.ucr.gov.*

Alex B. Leath,

Chief Legal Officer, Unified Carrier Registration Plan.

[FR Doc. 2020–03252 Filed 2–13–20; 4:15 pm]

BILLING CODE 4910–YL–P

DEPARTMENT OF VETERANS AFFAIRS

Funding Availability: Homeless Providers Grant and Per Diem Program

AGENCY: VA Homeless Providers Grant and Per Diem (GPD) Program, Veterans Health Administration, Department of Veterans Affairs (VA).

ACTION: Notice of funding availability (NOFA).

SUMMARY: VA is announcing the availability of funds to eligible entities to provide per diem payments for the Transition in Place (TIP) housing model to facilitate housing stabilization for Veterans who are homeless or at risk of becoming homeless under VA's Homeless Providers GPD Program. VA expects to award funding to pay per diem for approximately 450 beds with this NOFA.

DATES: Applications for grants under the GPD Program must be received by the GPD National Program Office by 4:00 p.m. Eastern Time on Wednesday, April 22, 2020. In the interest of fairness to all competing applicants, this deadline is firm as to date and hour. VA will treat any application that is received after the deadline as ineligible for consideration. Applicants should take this practice into account and submit their materials early to avoid the risk of unanticipated delays, computer service outages, or other submission-related problems that might result in ineligibility.

For a Copy of the Application Package: The required documentation for applications is outlined under the Application Documentation Required sections of this NOFA. Questions should be referred to the GPD National Program Office by email at: *GPDgrants@va.gov.* For detailed GPD Program information and requirements, see part 61 of title 38, Code of Federal Regulations (CFR) or 38 CFR part 61.

Submission of Application Package: Applicants must submit applications electronically by following instructions found at: *www.va.gov/homeless/gpd.asp.* Applications may not be mailed, emailed, or sent by fax. Applications must be received by the GPD National Program Office by 4:00 p.m. Eastern Time on the application deadline date. Applications must be submitted as a complete package. Materials arriving separately will not be included in the application package for consideration and may result in the application being rejected or not funded.

Technical Assistance: Information regarding how to obtain technical assistance with the preparation of a grant application is available on the GPD Program website at: *www.va.gov/homeless/gpd.asp.*

FOR FURTHER INFORMATION CONTACT: Jeffery Quarles, Director, GPD Program, (673/GPD), VA National Grant and Per Diem Program Office, 10770 N 46th Street, Suite C–200, Tampa, FL 33617, (813) 979–3570. (This is not a toll-free number); *GPDGrants@va.gov.*

SUPPLEMENTARY INFORMATION: *Funding Opportunity Title:* GPD Per Diem Only Grant Program TIP.

Announcement Type: Initial.

Funding Opportunity Number: VA–GPD–TIP–FY2020.

Catalog of Federal Domestic Assistance Number: 64.024, VA Homeless Providers Grant and Per Diem Program.

I. Funding Opportunity Description

A. *Purpose:* This NOFA announces the availability of per diem funding to 501(c)(3) and 501(c)(19) non-profit organizations, state and local governments, and recognized Indian Tribal governments. Religious or faith-based organizations are eligible, on the same basis as any other organization, to apply to participate in this VA program. Faith-based organizations should refer to 38 CFR 61.64(b) through 61.64(g) for grant compliance requirements. Each

application must include a minimum of 5 TIP beds and up to a maximum of 20 TIP beds, per VA medical center (VAMC) catchment area, per each applicant's Employer Identification Number (EIN). Each applicant may request a maximum amount of per diem not to exceed $1.6 million total costs for the entire 3-year grant period. Applicants may request no more than $80,000 total costs per bed over the entire 3-year grant period based on the average number of beds to be provided as stated in the grant application. If more than one application per VAMC catchment area per applicant's EIN is received by the due date and time, VA will consider only one application. VA reserves the right to select which application to consider based on the submission dates and times or based on other factors.

Note: Applicants do not have to include coverage for the entire VAMC catchment area in the application. The coverage area, however, must not exceed the VAMC catchment area identified in the application. If an applicant does not know their VAMC catchment area, they can contact the local medical facility provided at the following address: *www.va.gov/directory/guide/allstate.asp* and ask to speak with the Homeless Program. Applicants are encouraged to tailor their proposed coverage area to factors such as their own ability and the particular needs of the community.

Applicants agree to meet the applicable requirements of 38 CFR part 61 as a part of the effort to end homelessness among our Nation's Veterans.

B. *Definitions:* Title 38 CFR part 61 contains definitions of terms used in the GPD Program that are applicable to this NOFA.

C. *Eligibility Information:* To be eligible, an applicant must be a 501(c)(3) or 501(c)(19) non-profit organization, state or local government, or recognized Indian Tribal government that meets the requirements in 38 CFR 61.1. Religious or faith-based organizations are eligible, on the same basis as any other organization, to participate in this VA program. Faith-based organizations should refer to 38 CFR 61.64(b) through 61.64(g) for grant compliance requirements.

D. *Cost Sharing or Matching:* None.

E. *Authority:* Funding applied for under this NOFA is authorized by 38 U.S.C. 2011, 2012.

F. *TIP Housing Model Description:*

Note: The model description below has *Required Minimum Performance Metrics/Targets* that are set for the award period (October 1, 2020–September 30, 2023). VA may, at its discretion, update these targets at any point during the award period. If any new targets come into effect, VA will notify grantees in writing.

Transition in Place

Targeted Population—Homeless Veterans who choose a supportive transitional housing environment providing services prior to entering permanent housing.

Model Overview—Provides transitional housing and robust services that facilitate individual stabilization, increased income, and movement of the Veteran to permanent housing in the residence as rapidly as clinically appropriate.

Characteristics & Standards—The TIP housing model offers Veteran residents housing in which supportive services transition out of the residence over time, rather than the resident. This leaves the resident in place at the residence and not forced to find other housing while stabilizing. It is expected that Veterans will transition in place in approximately 6 to 12 months. Applicants should be aware that for an extension beyond 12 months, prior written approval from the GPD Liaison would be required, and extensions would be considered in increments of up to 90 days at a time and generally not to exceed a combined total of up to 24 months per Veteran. This model does not support discharge planning that would have the Veteran transition to the Department of Housing and Urban Development–VA Supportive Housing (HUD–VASH) as the HUD–VASH Program targets a Veteran population in need of specialized case management. Similarly, this grant does not support discharge planning to Supportive Services for Veteran Families (SSVF) Rapid Rehousing.

Scope of services should incorporate tactics to increase the Veteran's income through employment and/or benefits and to secure the permanent housing in the Veteran's name. Services provided and strategies used by the applicant will vary based on the individualized needs of the Veteran and resources available in the community. Housing case management should be flexible in intensity, support client choice, use a strengths-based approach, and focus on housing retention and helping the household to develop, enhance, or re-engage a network of support that will continue with them after they finish TIP. Case managers are expected to work on tenancy support such as how to resolve conflicts, how to understand a lease, options for working through crises and other skills that will assist them in retaining housing when they are no longer in TIP. Applicants specify the staffing levels and range of services to be provided, which are expected to be multidisciplinary and robust.

Applicants identify or convert existing suitable apartment-style housing where homeless Veteran participants would receive intensive, time-limited, supportive services optimally for a period of 6–12 months, but sometimes longer, as described above with prior written approval from the GPD Liaison for extensions in increments of up to 90 days at a time and generally not to exceed a combined total of up to 24 months per Veteran. Upon completion, the Veteran must be able to ''transition in place'' by assuming the lease or other long-term agreement which enables the unit in which he or she resides to be considered the Veteran's permanent housing. Grantees are expected to replace units as they are converted to permanent housing to maintain the average number of bed days as stated in the application during the entire grant period. Once the Veteran assumes the lease or other long-term agreement, VA will no longer provide funding for the unit under this NOFA. For example, each time a Veteran assumes the lease or other long-term agreement for the apartment, the grantee must identify a new unit in which to place another Veteran. By program design, transition to permanent housing should occur as rapidly as possible, and grantees should continually be acquiring and coordinating with VA on the inspection of new units to maintain a steady number of Veterans served.

Applicants applying under this NOFA must own or lease apartments intended as permanent housing for an individual or single family. Apartments must meet the inspection standards outlined at title 38 CFR 61.80 and have the following characteristics:

1. Private access without unauthorized passage through another dwelling unit or private property;
2. Sanitary facilities within the unit;
3. Basic furnishings and living supplies (including, at minimum, a bed, chairs, table, and cookware); and
4. Suitable space and equipment within the unit to store, prepare, and serve food in a sanitary manner (including, at a minimum, a refrigerator, freezer, sink, and stove). *Note:* Microwave ovens, hot plates, or similar items are not suitable substitutes for an operational stove.

Required Minimum Performance Metrics/Targets—VA has established performance metrics/targets for all successful applicants. Discharge to permanent housing is 75 percent.

Employment of individuals at discharge is 55 percent. Negative exits are less than 20 percent. Negative exits are defined as those exits from a GPD program for a violation of program rules, failure to comply with program requirements, or leaving the program without consulting staff. VA may, at its discretion, update these targets at any point during the award period. If any new targets come into effect, VA will notify grantees in writing.

Participant Agreement Information

Lease Guarantors—A Lease Guarantor is a third party (in this case, the grantee) who guarantees to pay the lease costs if the lessee (in this case, the Veteran) defaults. This is not allowed under this program.

Sublease—The sublease is a lease by a lessee (in this case, the grantee) to a third party (in this case, the Veteran) conveying the leased property for a shorter term than that of the lessee, who retains a reversion in the lease. For the sake of clarity, in a sublease TIP housing scenario, the landlord is the lessor, the grantee is the lessee, and the Veteran is the sublessee.

GPD TIP grantees may use subleases during the transitional housing phase if the sublease has been approved by the GPD National Program Office, and the sublease meets the following conditions:

1. Period of sublease must be less than the entire period of the grantee's lease with the landlord.
2. Grantee lease renewal must be taken into consideration when stating the period of the sublease.
3. Sublease must be explicit that the grantee is the lessee, not the Veteran.
4. Sublease must revert back to the grantee lessee without sanctions to the Veteran should the Veteran leave prior to program completion and lease assumption.
5. Sublease may not contain requirements contrary to GPD regulations.
6. Security deposits may not be charged to Veterans. However, grantee lessees may take other available and appropriate legal steps in situations of property destruction.

Lease Assumption—When a third party (in this case the Veteran) assumes a lease, the original lessee does not retain any interest in the lease.

Low Income Housing Tax Credits—Grantees that use tax credit programs may request that Veterans fill out a tax credit application, as there is no prohibition in GPD regulations. The issues that could arise are operational and specific to GPD TIP. The following are two examples.

Example 1. Under the GPD TIP for which the grantee is funded, the Veteran may not ''assume'' a lease until the transitional housing phase is complete. A sublease may be used as long as it meets the requirements above. If the grantee is not leasing from another landlord, it will make a difference. As the relationship changes, the grantee is the lessor and the Veteran becomes the lessee. This is not a sublease. In this case some other form of program agreement may have to be used that meets the elements of items 4, 5, and 6 above and meets tax credit requirements.

Example 2. Income under tax credits is calculated differently than in GPD. The grantee must follow GPD regulations during the transitional phase, and only the Veteran's income may be counted as defined in 38 CFR 61.82. When the Veteran completes the program and then ''assumes'' the lease, the calculation of income will revert to the tax credit requirements. The Veteran should be apprised of this prior to program entry so appropriate planning can be put into place.

II. Award Information

A. *Allocation of funds:* Funding awarded under this NOFA will be for a period of 3 years, beginning on October 1, 2020, and ending on September 30, 2023, dependent upon factors such as funding availability, the recipient meeting the performance goals established in the grant agreement, utilization rates of beds or services, statutory and regulatory requirements, and the results of the VA inspection. Continuation of funding is not guaranteed.

B. *Funding Restrictions:* No part of an award under this NOFA may be used to facilitate capital improvements or to purchase vans or real property. Questions should be directed to VA's GPD National Program Office at the email address listed in the contact section of the NOFA. Applicants may not receive funding to replace funds provided by any Federal, state, or local government agency or program to assist homeless persons.

C. *Funding Limitations:*

1. VA's decisions will be based on factors such as need, geographic dispersion, and availability of funding.
2. Each application must include a minimum of 5 TIP beds and up to a maximum of 20 TIP beds, per VAMC catchment area, per each applicant's EIN.
3. Each applicant may request a maximum amount of per diem not to exceed $1.6 million total costs for the entire 3-year grant period. Applicants may request no more than $80,000 total costs per bed over the entire 3-year grant period based on the average number of beds to be provided as stated in the grant application.

III. Application and Submission Information

A. *To Obtain a Grant Application:* Applicants must submit applications electronically following instructions found at: *www.va.gov/homeless/gpd.asp.* The required documentation for an application submission is outlined below in the Application Documentation Required, section IV of this NOFA. Standard forms, which must be included as part of a complete application package, may be downloaded directly from VA's GPD Program website at: *www.va.gov/homeless/gpd.asp.* Questions should be referred to the GPD National Program Office at: *GPDGrants@va.gov.* For detailed GPD Program information and requirements, see 38 CFR part 61.

B. *Content and Form of Application:* VA is seeking to focus resources to assist Veterans who are homeless or at risk of becoming homeless. If your agency is unclear as to how to apply, contact the GPD National Program Office for clarification prior to submission of any application to ensure it is submitted in the correct format.

Applicants should ensure that they include all required documents in their electronic application submission, carefully follow the format and provide the information requested and described below. Submission of an incorrect, incomplete, or incorrectly formatted application package will result in the application being rejected.

IV. Application Documentation Required

A. *Standard Forms (SF) and budget information:*

1. Application for Federal Assistance (SF–424).
2. Indirect cost information: Applicants that have a negotiated indirect cost rate agreement must provide a copy of the agreement as an attachment to the application if they wish to charge indirect costs to the grant. Applicants without a negotiated indirect cost rate agreement may request the *de minimis* rate for indirect costs if they meet the definitions and requirements of 2 CFR part 200. All other allowable costs will be considered only if they are direct costs.

B. *Eligibility:* State/local government entities must provide as an attachment to the application a copy of any comments or recommendations by approved state and area-wide

clearinghouses pursuant to Executive Order 12372.

C. *System for Award Management (SAM):* Applicants must provide a current Data Universal Numbering System (DUNS) number, Unique Entity Identifier (UEI) and SAM expiration date.

D. *Project Summary:*

1. Name and station number of the VAMC whose catchment area includes the transitional housing location(s) requested in this application. If requesting multiple sites, all sites must fall within the same VAMC catchment area. If requesting multiple sites, applicants should make sure each proposed site is strongly justified and well developed. The quality of each site will impact the overall score of the application.

2. Name(s) and number(s) of the Continuum of Care (CoC) where the transitional housing requested in this application will be located. If requesting sites in multiple CoCs, applicants should make sure sites in each CoC are strongly justified and well developed. The quality of sites in each CoC will impact the overall score of the application.

3. Number of beds for which your agency is requesting per diem in this application. Total request to VA for all beds for the entire 3-year period.

4. Location of housing provided under this application. For fixed sites, identify the address, city, state, zip code + four-digit extension, county, other counties served, congressional district, the number of GPD beds at each location, and gender(s) served. For sites whose locations are not available at the time of application, provide the names of all counties in which services will be provided.

5. Per location, a description of how the facility's participant living space will be configured. Include the square footage of the room or unit, the number of beds in that square footage and other descriptive information (*e.g.,* Single Room Occupancy, 100 square feet, no bunk beds; Apartment(s), 1,500 square feet, 1, 2, or 3 bedroom(s), no bunk beds). Identify any differences between locations, if applicable.

6. Description of whether your agency currently uses the Homeless Management Information System (HMIS) and if so, describe your participation with HMIS. HMIS is a locally-administered Web-based data system used to record and analyze both program and client information at the local CoC level. It is used by other Federal partners, including VA, to measure project performance and participate in benchmarking of the national effort to end homelessness. Currently, using HMIS is optional for GPD grantees. However, it can be a useful tool for program monitoring and also for coordination with community partners. Additionally, many communities use HMIS to conduct Coordinated Entry assessments. Applicants should be connected to Coordinated Entry, the Veteran Master List/By Name List, and Case Conferencing to support referrals to the program.

E. *Applicant Contact Information:*

1. Location of the administrative office where correspondence can be sent to the Executive Director/President/Chief Executive Officer (CEO) (no Post Office Boxes). Include complete address, city, state, zip code + four-digit extension, county, and congressional district.

2. *Organization Primary Contact:* Include the name, title, phone, and email address. Note: GPD views the organization primary contact as assigned to the organization, not a specific grant award, and should be someone who normally signs grant agreements or makes executive decisions for the organization. This is most often the Executive Director, the President, or the CEO. Organizations with multiple awards can only have one Organization Contact.

3. *Grant Contact #1:* Include the name, title, phone, and email address. *Note:* This contact is specific to this grant application and may be a Program Manager, Director, Case Manager, Grant Administrator, or other position overseeing the GPD grant project.

4. Provide as an attachment to the application a complete listing of your agency's officers of the Board of Directors and each person's address, phone, and email address.

F. *Project Abstract:* In approximately 500 words, provide a brief abstract of the proposed project. As applicable, include a discussion of multiple sites, multiple CoCs, and/or other information relevant to an understanding of the overall project.

G. *Detailed Application Design:* This is the portion of the application that describes your proposed program. VA reviewers will focus on how the detailed application design addresses the areas of outreach, project plan, ability, need, and coordination including how supportive services will be coordinated. VA expects applicants awarded under this NOFA will meet the VA performance metrics. With those metrics in mind, and in response to the following sections, please include strategies to meet or exceed VA's national metric targets. Applicants are encouraged to discuss specifics about their case management intervention approaches within each of the questions below, as applicable. Applications that demonstrate intensive approaches to case management that are strengths-based, evidence-based, multidisciplinary, multiphasic, structured, flexible in intensity, and integrated with personal networks and with the VA or mainstream community that will be most responsive to this NOFA. Examples include critical time intervention (CTI), motivational interviewing, progressive engagement/progressive assistance, and other approaches or a combination of approaches. The requirements in this section are consistent with 38 CFR part 61.

(a) *Outreach (see 38 CFR 61.13(c)):* This is the portion of the application where applicants will discuss how the outreach plan is tailored to the project and how services will be provided to Veterans living in places not ordinarily meant for human habitation (*e.g.,* streets, parks, abandoned buildings, automobiles, emergency shelters). Applications will be scored on responses to the following questions:

1. Outreach—In approximately 250 words, describe your agency's plan to conduct outreach, including frequency of outreach, to your selected Veteran population(s) living in places not ordinarily meant for human habitation (*e.g.,* streets, parks, abandoned buildings, automobiles, emergency shelters).

2. Outreach—In approximately 1,000 words, describe where your organization will target and tailor its outreach efforts to identify appropriate Veterans for this program. Additionally, applicants should discuss their plans for orienting Veterans about the program's process and timeline prior to enrollment.

3. Outreach—In approximately 500 words, describe your agency's involvement in the Coordinated Assessment/Entry efforts of the CoC(s) named in Project Summary question IV.D.2. and how this project would be involved in coordinated entry efforts. Describe how your organization's outreach plan fits into each CoC's plan to end homelessness.

(b) *Project Plan (see 38 CFR 61.13(b)):* VA wishes to provide the most appropriate housing based on the needs of the individual Veteran. Applications will be scored on responses to the following questions:

1. Project Plan— In approximately 2,000 words, provide a list of the supportive services offered to help participants achieve residential

stability, increase skill level and/or income, and become involved in making life decisions that will increase self-determination. This list should include a brief description of the service; the minimum frequency that the service will be offered; and the job title, including minimum credentials of the individual(s) who will provide the service. It is expected that these services be available during flexible hours (*e.g.,* accommodating for participants who are employed or have other obligations) and that case management services, to the extent possible, include regular home visits, when appropriate. Applicants are expected to provide intensive services that are strengths-based, evidence-based, multidisciplinary, multiphasic, structured, flexible in intensity, and integrated with personal networks and with the VA or mainstream community. Applicants who are employing a formal approach to services such as CTI, motivational interviewing, progressive engagement/progressive assistance, and other approaches or a combination of approaches, should include descriptions accordingly.

2. Project Plan—In approximately 500 words, describe the specific process and criteria for deciding which Veterans are appropriate for admission.

3. Project Plan—In approximately 500 words, address whether the project will serve mixed gender populations and/or individuals with children. Provide a listing and explanation of any gender-specific services.

4. Project Plan—In approximately 500 words, describe how the safety, security, and privacy of participants will be ensured.

5. Project Plan—In approximately 500 words, provide your agency's Individual Service Plan (ISP) methodology and the core items to be addressed in the ISP. The goal is to ensure that Veterans have the tools they need to maximize their ability to pay rent, to understand landlord/tenant rights and responsibilities, and to be proactive in addressing issues that may have contributed to a loss of housing in the past. Additionally, applicants should describe their plans for various phases of the program including how to identify when it is appropriate to transition and how progress could be completed within a period of 6–12 months. Applicants should be aware that for an extension beyond 12 months, prior written approval from the GPD Liaison is required. Extensions would be considered in increments of up to 90 days at a time and generally not to exceed a combined total of up to 24 months per Veteran.

6. Project Plan—In approximately 500 words, describe how, when, and by whom participants' progress toward meeting their individual goals will be monitored, evaluated, and documented. Include descriptions of how progress notes, case conferencing, and supervision will be documented. Applicants are expected to provide intensive case management that is strengths-based, evidence-based, multidisciplinary, multiphasic, structured, flexible in intensity, and integrated with personal networks and with the VA or mainstream community. This approach to case management usually would involve a team of clinicians, case managers, and if applicable, social worker(s), nurse(s), or other appropriate personnel with skills in community-based service delivery.

7. Project Plan—In approximately 500 words, describe how you will work with Veterans to help them gain skills to assist in retaining housing after TIP support ends. Describe how you will determine when the Veteran is ready to assume the lease or long-term agreement. Additionally, applicants should describe how exceptional cases will be handled (*e.g.,* cases in which Veterans need more or less than the usual time to complete the program).

8. Project Plan—In approximately 500 words, describe how you will ensure that each Veteran receives individualized services to meet permanent housing goals. Indicate how the program plans to meet VA's metrics/targets and meet the goals of the community within which the grantee is working.

9. Project Plan—In approximately 500 words, describe how necessary follow-up services will be provided. For example, the Project Plan should describe how often they will occur and the duration of the follow up.

10. Project Plan—In approximately 500 words, describe how Veteran participants will have a voice and aid in operating and maintaining the housing (*e.g.,* volunteer time, paid positions, community governance meetings, peer support).

11. Project Plan—In approximately 500 words, if your agency plans to use any subrecipient(s) and/or contractor(s) for operating and/or maintaining the housing, describe the responsibilities of the subrecipient(s) and/or contractor(s).

12. Project Plan—In approximately 500 words, describe program policies regarding a clean and sober environment. Include in the description how participant relapse will be handled and how these policies will affect the admission and discharge criteria.

13. Project Plan—In approximately 500 words, provide and describe the type and implementation of the medication control system that will be used in this project (*e.g.,* Medication Management, Medication Monitoring, individual storage). For reference, applicants may review these requirements at: *www.va.gov/homeless/gpd.asp.*

14. Project Plan—In approximately 250 words, describe program polices regarding participant agreements, including any leases and subleases, if used.

15. Project Plan—In approximately 250 words, describe program polices regarding extracurricular fees.

16. Project Plan—In approximately 500 words, describe how you will aid Veterans who seek employment and income maximization goals, such as increased income, increased benefits, reduced expenses, or improved financial management skills. Please note that services such as Supplemental Security Income and Social Security Disability Insurance (SSI/SSDI) Outreach, Access, and Recovery (SOAR) and other income maximization strategies may be used by applicants.

17. Project Plan—In approximately 500 words, address how your agency will facilitate the provision of nutritional meals for the Veterans. Be sure to describe how Veterans with little or no income will be assisted.

18. Project Plan—In approximately 250 words, describe how you will facilitate transportation of the Veteran participants to appointments, employment, and supportive services.

(c) *Ability (see 38 CFR 61.13(d)):* This is the portion of the application where applicants demonstrate their ability to develop, operate, and complete the project with necessary staff and experience regarding the selected population(s). Applications will be scored on responses to the following questions:

1. Ability—Provide as an attachment to the application a table or spreadsheet of the staffing plan for this project (see Example 3). Do not include resumés. Information provided here should be consistent with information provided in project plan question number 6 and with information provided elsewhere in the application.

Example 3:

Job title	Brief (1–2 sentence) description of responsibilities	Educational level	Hours per week allocated to GPD project (40 hours equals full-time)	Amount of annual salary allocated to the GPD project	Amount of salary for the full-time position
Case Manager	Responsible for working with the Veteran to develop and monitor an individual service plan and to adjust the plan, as needed. Coordinates support with other community agencies.	BSW	30 hours	$60,000	$80,000

2. Ability—In approximately 500 words, describe your agency's previous experience assessing and providing for the housing needs of homeless Veterans.

3. Ability—In approximately 500 words, describe your agency's previous experience assessing and providing supportive services to homeless Veterans. Applicants should describe their previous experience, if any, using and receiving training in intensive case management services to homeless Veterans that are strengths-based, evidence-based, multidisciplinary, multiphasic, structured, flexible in intensity, and integrated with personal networks and with the VA or mainstream community. Applicants with previous experience in formal approaches such as CTI, motivational interviewing, progressive engagement/progressive assistance, and other formal approaches, should include descriptions accordingly.

4. Ability—In approximately 500 words, describe your agency's ability to get the project started within 180 days from the potential award date. Describe the start-up activities, the timing involved, and when the project would be expected to be fully functional.

5. Ability—In approximately 500 words, describe your agency's previous experience in assessing supportive service resources and entitlement benefits.

6. Ability—In approximately 500 words, describe your agency's previous experience with evaluating the progress of both individual participants and overall program effectiveness using quality and performance data to make changes. Describe your agency's experience with meeting past performance goals. Do not include past inspection forms or past VA performance reports with the application.

7. Ability—In approximately 250 words, describe whether your agency is accredited and/or licensed to provide clinical services. If yes, describe your agency's accreditation and/or licensure. If applicable, include specific details, such as training completion dates, training titles, and training providers. Some generally accepted accreditations include: (1) Commission on Accreditation of Rehabilitation Facilities in Community Employment Services or in Rapid Rehousing and Homeless Prevention Program; (2) a 4-year accreditation from the Council on Accreditation's accreditation in Housing Stabilization and Community Living Services standards; and (3) a 3-year accreditation in the Joint Commission's Behavioral Health Care: Housing Support Services Standards; among others.

8. Ability—In approximately 500 words, describe the organization's staff development plan to help staff gain and maintain the knowledge, skills, and abilities to provide culturally competent and relevant related services to people impacted by racial inequity. Include details on how staff will participate in specific training activities.

(d) *Need (see 38 CFR 61.13(e)):* This is the portion of the application where applicants demonstrate that the proposed project is necessary. Applications will be scored on responses to the following questions:

1. Need—In approximately 500 words, describe how this project is tailored to the particular needs of the CoC(s) and fit with the strategy of the CoC(s) to end homelessness. Cite reliable data from surveys of homeless populations or other reports or data-gathering mechanisms. Additionally, applicants should describe how caseloads will be kept low (typically 20 or less per case manager) while also meeting the community's need. Note: If multiple CoCs are named in the Project Summary question IV.D.2, your response here should discuss each of those CoCs.

2. Need—In approximately 500 words, describe with whom you consulted outside of your agency to determine the need for the proposed project within the CoC(s). Note: If multiple CoCs are named in the Project Summary question IV.D.2, your response here should discuss each of those CoCs.

(e) Coordination (see 38 CFR 61.13(g)): This is the portion of the application where applicants will demonstrate their involvement in the homeless Veteran continuum. Applications will be scored on responses to the following questions:

1. Coordination—In approximately 500 words, describe how your agency is part of an ongoing community-wide planning process to end Veteran homelessness. Note: If multiple CoCs are named in the Project Summary question IV.D.2, your response here should discuss each of those CoCs.

2. Coordination—In approximately 500 words, describe how your process is designed to share information on available resources and reduce duplication among programs that serve homeless Veterans. Note: If multiple CoCs are named in the Project Summary question IV.D.2, your response here should discuss each of those CoCs. Applicants who wish to provide a letter(s) of coordination from the local CoC(s) must attach a letter at the end of the application. Applicants are strongly encouraged to allow as much time as possible, and no less than 30 days, for a CoC to provide a letter of coordination. All application materials must be submitted together in a single package by the due date and time. Any materials arriving separately or late will not be accepted as part of the application.

3. Coordination—In approximately 500 words, describe how your agency has coordinated GPD services with other programs offered in the CoC(s) named in the Project Summary question IV.D.2.

4. Coordination—In approximately 250 words, describe how your agency consulted directly with the VAMC Director (or the appropriate authorized VAMC representative per the local VAMC's practice) regarding coordination of services for project

participants. Provide your plan to ensure access to health care, case management, and other care services. Applicants who wish to provide a letter of coordination from the local VAMC must attach a letter at the end of the application. Applicants are strongly encouraged to allow as much time as possible (not less than 30 days) for a VAMC to provide a letter of coordination. All application materials must be submitted together in a single package by the due date and time. Any materials arriving separately or late will not be accepted as part of the application.

5. Coordination—Applicants may attach to their application a letter(s) of coordination from their proposed multidisciplinary case management team partner(s) if applicable. Applicants are encouraged to provide a letter(s) of coordination if proposing a team consisting of partners external to the applicant organization (*e.g.,* personnel services hired or contracted through a third party or personnel services leveraged from other resources outside of grant funds). If including a letter(s) of coordination, applicants are strongly encouraged to allow as much time as possible (not less than 30 days) for a partner to provide a letter of coordination. All application materials must be submitted together in a single package by the due date and time. Any materials arriving separately or late will not be accepted as part of the application.

Note: Applicants should not provide self-report letters of coordination on their own internal operations. For example, if applicants are planning to hire a licensed social worker to coordinate care, they do not need to write a letter of coordination for themselves.

V. Application Review Information

A. *Criteria for Grants:* Submission of an incorrect, incomplete, or incorrectly formatted application package will result in the application being rejected at threshold. Applications that meet threshold will be scored according to the rating criteria described in 38 CFR 61.32 to score grant applications. Applications will then be ranked based on that score. The highest-ranking applications with a score of 750 or higher will be considered for funding in rank order as funding allows.

B. *Review and Selection Process:* Review and selection process may be found at 38 CFR 61.13 and 38 CFR 61.32.

C. *Tie Score:* In the event of a tie score between applications, VA will use the score from the Coordination section to determine the ranking, as required by 38 CFR 61.32(b). If further determinations are needed to break a tie, VA will decide at its discretion how to handle selection decisions (*e.g.,* selecting multiple applications for award, awarding for less than requested).

D. *Funding Actions:* Funding is not guaranteed. Conditionally-selected applicants will be asked to submit additional information under 38 CFR 61.32. Applicants will be notified of the deadline to submit such information. If an applicant is unable to meet any conditions for the grant award within the specified time, VA may non-select the applicant and may use the funding for another applicant(s). VA may negotiate bed numbers or other arrangements with conditionally-selected applicants and will incorporate any changes into the grant agreement. Prior to awarding a grant agreement, VA reserves the right to adjust up or down (*e.g.,* funding levels, bed numbers, locations) as needed within the intent of the NOFA based on a variety of factors including the quantity and quality of applications, as well as the availability of funding. VA may elect to award additional applications based on the availability of funds and quality of applications. Upon signature of the grant agreement by the Secretary, or designated representative, final selection will be completed, and the grant funds will be obligated for the funding period.

VI. Award Administration Information

A. *Award Notice:* Although subject to change, the GPD National Program Office expects to announce grant awards in the fourth quarter of Fiscal Year 2020. Awards will be for 3 years. Continuation funding is not guaranteed. VA reserves the right in any year to adjust up or down (*e.g.,* funding levels, bed numbers, locations) as needed within the intent of the NOFA based on a variety of factors including availability of funding and performance. The initial announcement will be made via news release which will be posted on VA's GPD National Program website at: *www.va.gov/homeless/gpd.asp.* Following the initial announcement, the GPD Office will send notification letters to the grant recipients. Applicants who are not selected will be sent a declination letter.

B. *Administrative and National Policy:* VA places great emphasis on responsibility and accountability. VA has procedures in place to monitor services provided to homeless Veterans and outcomes associated with the services provided under this GPD program. All awardees that are selected in response to this NOFA must meet the requirements of the current edition of the Life Safety Code of the National Fire Protection Association as it relates to their specific facility. Applicants should note that all facilities must be protected throughout by an approved automatic sprinkler system unless a facility is specifically exempt under the Life Safety Code. Applicants should consider this when submitting their grant applications, as no funds will be made available for capital improvements under this NOFA.

C. *Payment:* Per diem will be paid in a method that is in accordance with VA and other Federal fiscal requirements. The per diem payment will be at a rate not to exceed 1.5 times the current VA State Home Program per diem rate for domiciliary care as set by the Secretary under 38 United States Code (U.S.C.) section 2012 and 38 U.S.C. 1741(a)(1). The per diem payment calculation may be found at 38 CFR 61.33. Awardees will be subject to requirements of this NOFA, GPD regulations, 2 CFR part 200, and other Federal grant requirements. A full copy of the regulations governing the GPD Program is available at the GPD website at: *www.va.gov/homeless/gpd.asp.* Awardees will be required to support their request for payments with adequate fiscal documentation as to project income and expenses. Awardees that have a negotiated indirect cost rate agreement must provide GPD with an updated copy annually or when available.

D. *Reporting:*

1. Upon execution of a grant agreement with VA, grantees will have a liaison appointed from a nearby VAMC to provide oversight and monitor services provided to homeless Veterans in the program.

2. Monitoring will include, at a minimum, a quarterly review of each per diem program's progress toward meeting VA's performance metrics, helping Veterans attain housing stability, adequate income support, and self-sufficiency as identified in the application. Monitoring may also include a review of the agency's income and expenses as they relate to this project to ensure payment is accurate and to ensure compliance with program requirements. The grantee will be expected to demonstrate adherence to the grantee's proposed program concept, as described in the grantee's application. All grantees are subject to audits conducted by VA or its representative.

3. Each funded program will participate in VA's national program monitoring and evaluation as these procedures will be used to determine successful accomplishment of housing,

employment, and self-sufficiency outcomes for each per diem-funded program. Note: The model description above has *Required Minimum Performance Metrics/Targets* that are set for the award period (October 1, 2020–September 30, 2023). VA may, at its discretion, update these targets at any point during the award period. If any new targets come into effect, VA will notify grantees in writing.

4. It is expected that Veterans will transition in place in approximately 6 to 12 months. Grantees should be aware that for an extension beyond 12 months, prior written approval from the GPD Liaison would be required. Extensions would be considered in increments of up to 90 days at a time and generally not to exceed a combined total of up to 24 months per Veteran.

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. Pamela Powers, Chief of Staff, Department of Veterans Affairs, approved this document on February 12, 2020, for publication.

Luvenia Potts,

Regulation Development Coordinator, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2020–03108 Filed 2–14–20; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on the Readjustment of Veterans, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act that a meeting of the Department of Veterans Advisory Committee on the Readjustment of Veterans will be held on Monday, March 16–Wednesday, March 18, 2020, at 811 Vermont Avenue (The Lafayette Building), Conference Room 3172/3174, Washington, DC 20420. The meeting sessions will begin and end as follows:

Date	Time
March 16, 2020	9:00 a.m. to 5:00 p.m. EST.
March 17, 2020	9:00 a.m. to 5:00 p.m. EST.
March 18, 2020	9:00 a.m. to 12:00 p.m. EST.

The meetings sessions are open to the public.

The Committee, comprised of 12 subject matter experts, advises the Secretary, through the VA Readjustment Counseling Service, on the provision by VA of benefits and services to assist Veterans in the readjustment to civilian life. In carrying out this duty, the Committee assembles, reviews, and assesses information relating to the needs of Veterans readjusting to civilian life and the effectiveness of VA services in assisting Veterans in that readjustment, specifically taking into account the needs of Veterans who served in combat theaters of operation.

On March 16, 2020, the agenda will include a training session regarding the roles and responsibilities of the individuals as Committee members, a review of the legislation which gave birth to the Committee, historical perspective, and welcoming remarks from VA officials on new and ongoing VA initiatives and priorities regarding this specific population of interest. On March 17, 2020, the agenda will include a report from the subcommittee on work accomplished in the past year, and additional remarks by VA officials on ongoing VA initiatives and priorities. On March 18, 2020, the morning will include planning session for the work to be accomplished during the course of the year.

No time will be allotted for receiving oral comments from the public; however, the public can submit written statements for the Committee's review to Ms. Sherry Moravy, Designated Federal Officer, Readjustment Counseling Service (10RCS), Department of Veterans Affairs, 1717 H Street NW, Washington, DC 20420, or by email at *VHA10RCSAction@va.gov.* Any member of the public wishing to attend the meeting or seeking additional information should contact Ms. Moravy at the phone number (734) 222–4319 or email address noted above.

Dated: February 11, 2020.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2020–03086 Filed 2–14–20; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 417, 422, et al.

Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 417, 422, 423, 455, and 460

[CMS–4190–P]

RIN 0938–AT97

Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise regulations for the Medicare Advantage (Part C) program, Medicare Prescription Drug Benefit (Part D) program, Medicaid program, Medicare Cost Plan program, and Programs of All-Inclusive Care for the Elderly to implement certain sections of the Bipartisan Budget Act of 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, and the 21st Century Cures Act. This proposed rule would also enhance the Part C and D programs, codify several existing CMS policies, and implement other technical changes.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on April 6, 2020.

ADDRESSES: In commenting, please refer to file code CMS–4190–P. 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: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4190–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4190–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:
Theresa Wachter, (410) 786–1157, or Cali Diehl, (410) 786–4053—General Questions.
Kimberlee Levin, (410) 786–2549—Part C Issues.
Lucia Patrone, (410) 786–8621—Part D Issues.
Kristy Nishimoto, (206) 615–2367—Beneficiary Enrollment and Appeals Issues.
Stacy Davis, (410) 786–7813—Part C and D Payment Issues.
Sabrina Sparkman, (410) 786–3209—PACE Issues.
Debra Drew, (410) 786–6827—Program Integrity Issues.
Melissa Seeley, (212) 616–2329—D–SNP Issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Acronyms

AE Actuarial Equivalent
AEP Annual Coordinated Enrollment Period
AIC Amount in Controversy
ANOC Annual Notice of Change
ARB At-Risk Beneficiaries
BBA Bipartisan Budget Act
BBP Base Beneficiary Premium
BLS Bureau of Labor Statistics
CAHPS Consumer Assessment of Healthcare Providers and Systems
CARA Comprehensive Addiction and Recovery Act
CDC Centers for Disease Control and Prevention
CEAC Counties with Extreme Access Considerations
CMS Centers for Medicare & Medicaid Services
COI Collection of Information
CON Certificate of Need
COPD Chronic Obstructive Pulmonary Disease
C–SNP Chronic Condition Special Needs Plan
DME Durable Medical Equipment
DMP Drug Management Program
D–SNP Dual Eligible Special Needs Plan
ED Emergency Department
EGWP Employer Group Waiver Plan
EHR Electronic Health Record
EOC Evidence of Coverage
eRx E-Prescribing
ESRD End-Stage Renal Disease
FAD Frequently Abused Drug
FAQ Frequently Asked Question
FFS Fee-for-Service
FIDE SNP Fully Integrated Dual Eligible Special Needs Plan
FMV Fair Market Value
HEDIS Healthcare Effectiveness Data and Information Set
HHS Department of Health and Human Services
HIDE SNP Highly Integrated Dual Eligible Special Needs Plan
HIPAA Health Insurance Portability and Accountability Act of 1996
HOS Health Outcomes Survey
HPMS Health Plan Management System
HSD Health Service Delivery
ICD International Classification of Diseases
ICR Information Collection Requirement
IDR Integrated Data Repository
IDT Interdisciplinary Team
IMF Illicitly Manufactured Fentanyl
IRE Independent Review Entity
IRMAA Income-Related Monthly Adjustment Amount
I–SNP Institutional Special Needs Plan
IT Information Technology
LPPO Local Preferred Provider Organization
MA Medicare Advantage
MACPAC Medicaid and CHIP Payment and Access Commission
MAGI Modified Adjusted Gross Income
MA–PD Medicare Advantage Prescription Drug
MCO Managed Care Organization
MCMG Medicare Communications and Marketing Guidelines
MCS Improving or Maintaining Mental Health
MedPAC Medicare Payment Advisory Commission
MIPPA Medicare Improvements for Patients and Providers Act
MLR Medical Loss Ratio
MMA Medicare Prescription Drug, Improvement, and Modernization Act
MMCM Medicare Managed Care Manual
MME Morphine Milligram Equivalent

MMP Medicare-Medicaid Plan
MOC Model of Care
MOOP Maximum Out-of-Pocket
MPF Medicare Plan Finder
MSA Medical Savings Account
NAICS North American Industry Classification System
NBI MEDIC National Benefit Integrity Medicare Drug Integrity Contractor
NCQA National Committee for Quality Assurance
NMM Network Management Module
NPPES National Provider and Plan Enumeration System
NQF National Quality Forum
OACT Office of the Actuary
OEP Open Enrollment Period
OIG Office of Inspector General
OMB Office of Management and Budget
OMHA Office of Medicare Hearings and Appeals
OMS Overutilization Management System
OUD Opioid Use Disorder
PA Prior Authorization
PACE Programs of All-Inclusive Care for the Elderly
PAD Peripheral Artery Disease
PARB Potential At-Risk Beneficiary
PBP Plan Benefit Package
PCS Improving or Maintaining Physical Health
PDE Prescription Drug Event
PDP Prescription Drug Plan
PFFS Private Fee-for-Service
PIM Program Integrity Manual
PMPM Per Member Per Month
POS Point-of-Sale
PQA Pharmacy Quality Alliance
PRA Paperwork Reduction Act
QBP Quality Bonus Payment
QIA Quality Improvement Activity
RFA Regulatory Flexibility Act
RI Rewards and Incentives
RPPO Regional Preferred Provider Organization
RTBT Real Time Benefit Tool
SAE Service Area Expansion
SAR Service Area Reduction
SB Summary of Benefits
SBA Small Business Administration
SCD Sickle Cell Disease
SEP Special Election Period
SET Supervised Exercise Therapy
SIU Special Investigations Unit
SMID Standardized Material Identification
SNP Special Needs Plan
SOA Scope of Appointment
SPAP State Pharmaceutical Assistance Program
SSA Social Security Administration
SSBCI Special Supplemental Benefits for the Chronically Ill
SUPD Statin Use in Persons with Diabetes
SUPPORT Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment
TMP Timeliness Monitoring Project
UM Utilization Management
UMRA Unfunded Mandates Reform Act

I. Executive Summary

A. Executive Summary

1. Purpose

The primary purpose of this proposed rule is to implement certain sections of the following federal laws related to the Medicare Advantage (MA or Part C) and Prescription Drug Benefit (Part D) programs:

- The Bipartisan Budget Act of 2018 (hereinafter referred to as the BBA of 2018)
- The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (hereinafter referred to as the SUPPORT Act)
- The 21st Century Cures Act (hereinafter referred to as the Cures Act)

The rule would also include a number of changes to strengthen and improve the Part C and D programs, codify in regulation several CMS interpretive policies previously adopted through the annual Call Letter and other sub-regulatory guidance documents, and implement other technical changes for contract year 2021 and 2022. In the fall of 2017, CMS launched the Patients over Paperwork initiative. The key focus of this initiative is to reduce ''red tape'' that depletes resources from our healthcare system and wastes the time clinicians and other healthcare workers need to perform their primary mission—caring for patients.

In keeping with the success of this program, CMS continues to review its regulatory requirements and sub-regulatory policies to examine opportunities to prioritize the well-being of patients over the CMS requirements on the healthcare industry. In particular, the Patients over Paperwork initiative charges CMS to analyze the impact of existing requirements and remove unnecessary burdens. As part of this, CMS is streamlining and clarifying certain patient protections and codifying important sub-regulatory guidance in the Code of Federal Regulations. This provides an opportunity for the public to review and comment on proposed requirements and provides transparency into CMS's rules and guidance.

2. Summary of the Major Provisions

a. Mandatory Drug Management Programs (DMPs) (§ 423.153)

Section 704 of the Comprehensive Addiction and Recovery Act of 2016 (hereinafter referred to as CARA) included provisions permitting Part D sponsors to establish drug management programs (DMPs) for beneficiaries at-risk for misuse or abuse of frequently abused drugs (FADs). Under the DMPs in place today, Part D sponsors engage in case management of potential at-risk beneficiaries (PARBs) through contact with their prescribers to determine whether the beneficiary is at-risk for prescription drug misuse or abuse. If a beneficiary is determined to be at-risk, after notifying the beneficiary in writing, the sponsor may limit their access to coverage of opioids and/or benzodiazepines to a selected prescriber and/or network pharmacy(ies) and/or through a beneficiary-specific point-of-sale (POS) claim edit.

While the majority of Part D sponsors have already voluntarily implemented DMPs, CMS is proposing the requirement of mandatory implementation of DMPs by Part D sponsors, for plan years beginning on or after January 1, 2022, as required under section 2004 of the SUPPORT Act.

b. Beneficiaries With History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)

A past overdose is the risk factor most predictive for another overdose or suicide-related event.[1] In light of this fact, in section 2006 of the SUPPORT Act, Congress required CMS to include Part D beneficiaries with a history of opioid-related overdose (as defined by the Secretary) as PARBs under a Part D plan's DMP. CMS is also required under this section to notify the sponsor of such identifications. In line with this requirement, we are proposing to modify the definition of ''potential at-risk beneficiary'' at § 423.100 to include a Part D eligible individual who is identified as having a history of opioid-related overdose, as we propose to define it. Inclusion of beneficiaries with a history of opioid-related overdose as PARBs in DMPs will allow Part D plan sponsors and providers to work together to closely assess these beneficiaries' opioid use and determine whether any additional action is warranted.

c. Automatic Escalation to External Review Under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries (§§ 423.153, 423.590, and 423.600)

CMS is proposing that, if on reconsideration a Part D sponsor affirms its denial of a DMP appeal, the case shall be automatically forwarded to the independent outside entity for review and resolution. We are proposing that a plan sponsor must forward the case to the independent outside entity by the expiration of the adjudication timeframe applicable to the plan level appeal. Finally, we are proposing conforming

[1] Bohnert KM, Ilgen MA, Louzon S, McCarthy JF, Katz IR. Substance use disorders and the risk of suicide mortality among men and women in the US Veterans Health Administration. Addiction. 2017 Jul;112(7):1193–1201. doi: 10.1111/add.13774.

revisions to the notices that are sent to beneficiaries.

d. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

CMS proposes to undertake rulemaking to implement the provisions outlined in sections 2008 and 6063 of the SUPPORT Act, which are summarized in the following sections (1) and (2). Implementing these provisions will allow CMS, MA organizations and Medicare Part D plan sponsors (including MA organizations offering MA–PD plans) to share data and information regarding bad actors, take swift action based on such data and information, and achieve enhanced outcomes in our efforts to fight the opioid crisis. In addition, this regulation will provide the means for more effective referrals to law enforcement based on plan sponsor reporting, ultimately resulting in reduced beneficiary harm and greater savings for the Medicare program.

(1) Section 2008 of the SUPPORT Act

Title XVIII of the Social Security Act (the Act) provides authority for CMS to suspend payments to Medicare fee-for-service (FFS) providers and suppliers pending an investigation of a credible allegation of fraud, unless a good cause exception applies. While Part D plan sponsors currently have the discretion to suspend payments to pharmacies in the plans' networks, section 2008 requires that plan sponsors' payment suspensions based on credible allegations of fraud be implemented in the same manner as CMS implements such payment suspensions. Under this provision, plan sponsors are required to notify the Secretary of the imposition of a payment suspension that is based on a credible allegation of fraud and may do so using a secure website portal. The reporting requirement applicable to plan sponsors will only apply to suspended payments based on credible allegations of fraud as required by section 2008 and will not extend to other payment suspensions for which plan sponsors already have authority. Section 2008 also clarifies that a fraud hotline tip, without further evidence, is not considered a credible fraud allegation for payment suspension purposes.

(2) Section 6063 of the SUPPORT Act

Section 6063 requires the Secretary to establish a secure internet website portal to enable the sharing of data among MA plans, prescription drug plans, and the Secretary, and referrals of ''substantiated or suspicious activities'' of a provider of services (including a prescriber) or a supplier related to fraud, waste, or abuse to initiate or assist with investigations conducted by eligible entities with a contract under section 1893 of the Act, such as a Medicare program integrity contractor. The Secretary is also required to use the portal to disseminate information to all MA plans and prescription drug plans on providers and suppliers that were referred to CMS for fraud, waste, and abuse in the last 12 months; were excluded or the subject of a payment suspension; are currently revoked from Medicare; or, for such plans that refer substantiated or suspicious activities to CMS, whether the related providers or suppliers were subject to administrative action for similar activities. The Secretary is required to define what constitutes substantiated or suspicious activities. Section 6063 specifies that a fraud hotline tip without further evidence shall not be treated as sufficient evidence for substantiated fraud, waste, or abuse.

Section 6063 also requires the Secretary to disseminate quarterly reports to MA plans and prescription drug plans on fraud, waste, and abuse schemes and suspicious activity trends reported through the portal. The Secretary's reports are to maintain the anonymity of information submitted by plans and to include administrative actions, opioid overprescribing information, and other data the Secretary, in consultation with stakeholders, determines important.

Beginning with plan year 2021, section 6063 also requires Part D plan sponsors to submit to the Secretary information on investigations, credible evidence of suspicious activities of providers or suppliers related to fraud, and other actions taken by the plans related to inappropriate opioid prescribing. The Secretary is required to issue regulations that define the term inappropriate prescribing with respect to opioids, identify a method to determine if providers are inappropriately prescribing, and identify the information plan sponsors are required to submit.

e. Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

The Cures Act (Pub. L. 114–255) amended sections 1851, 1852, and 1853 of the Act to expand enrollment options for individuals with end stage renal disease (ESRD) and make associated payment and coverage changes to the MA and original Medicare programs. Specifically, since the beginning of the MA program, individuals with ESRD have not been able to enroll in MA plans subject to limited exceptions. Section 17006(a) of the Cures Act removed this prohibition effective for plan years beginning on or after January 1, 2021. We are proposing to codify this change with revisions to §§ 422.50(a)(2), 422.52, and 422.110.

f. Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries (§ 422.322)

With this new enrollment option, the Cures Act also made several payment changes in the MA and original Medicare FFS programs. Section 17006(c) of the Cures Act amended section 1852(a)(1)(B)(i) of the Act to exclude from the Medicare benefits an MA plan is required to cover for an MA enrollee coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d) of the Act. Effective January 1, 2021, these costs will be covered under the original Medicare FFS program. Section 17006(c)(2) of the Cures Act also amended section 1851(i) of the Act, providing that CMS may pay an entity other than the MA organization that offers the plan in which the individual is enrolled for expenses for organ acquisitions for kidney transplants described in section 1852(a)(1)(B)(i) of the Act. We propose changes to our regulation at § 422.322 to align with these new statutory requirements.

g. Exclusion of Kidney Acquisition Costs From Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306)

Since the original Medicare FFS program will cover costs of organ acquisitions for kidney transplants for individuals in an MA plan, section 17006(b) of the Cures Act also amended section 1853 of the Act to exclude these costs from the MA benchmarks used in determining payment to MA plans. Specifically, the Secretary, effective January 1, 2021, is required to exclude the estimate of standardized costs for payments for organ acquisitions for kidney transplants from MA benchmarks and capitation rates. We propose changes to our regulations at §§ 422.258(d) and 422.306 to align with these new statutory requirements.

h. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)

In the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Final Rule (hereinafter referred to as the April 2018 final rule), we codified the methodology for the Star Ratings system for the MA and Part D programs, respectively, at §§ 422.160 through 422.166 and §§ 423.180 through 423.186. We will propose through rulemaking any changes to the methodology for calculating the ratings, the addition of new measures, and substantive measure changes.

At this time, in addition to routine measure updates and technical clarifications, we are proposing to further increase the weight of patient experience/complaints and access measures from a weight of 2 to 4. We are also proposing to directly remove outliers prior to calculating the cut points to further increase the predictability and stability of the Star Ratings system. We are also proposing to clarify some of the current rules around assigning Quality Bonus Payment (QBP) ratings and to codify existing policy for assigning QBP ratings for new contracts under existing parent organizations. Unless otherwise stated, data would be collected and performance measured using these proposed rules and regulations for the 2021 measurement period and the 2023 Star Ratings.

i. Permitting a Second, ''Preferred'', Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

We are proposing to allow Part D sponsors to establish up to two specialty tiers and design an exceptions process that exempts drugs on these tiers from tiering exceptions to non-specialty tiers. We propose that Part D sponsors would have the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the ingredient cost threshold established according to the methodology we are proposing and the requirements of the CMS formulary review and approval process under § 423.120(b)(2). To maintain Part D enrollee protections, we are proposing to codify a maximum allowable cost sharing that would apply to the higher cost-sharing specialty tier. Further, we propose to require that if there are two specialty tiers, one must be a ''preferred'' tier that offers lower cost sharing than the proposed maximum allowable specialty tier cost sharing.

We note that we are not proposing any revisions to § 423.578(c)(3)(ii), which requires Part D sponsors to provide coverage for a drug for which a tiering exception was approved at the cost sharing that applies to the preferred alternative. Because we propose that the exemption from tiering exceptions for specialty tier drugs would apply only to tiering exceptions to non-specialty tiers, our proposal would require Part D sponsors to permit tiering exception requests for drugs on the higher-cost specialty tier to the lower-cost specialty tier.

To improve transparency, we propose to codify current methodologies for cost sharing and calculations relative to the specialty tier, with some modifications. First, we propose to codify a maximum allowable cost sharing permitted for the specialty tiers of between 25 percent and 33 percent, depending on whether the plan includes a deductible, as described further in section V.F.4. of this proposed rule. We also propose to determine the specialty-tier cost threshold—meaning whether the drug has costs high enough to qualify for specialty tier placement—based on a 30-day equivalent supply. Additionally, we propose to base the determination of the specialty-tier cost threshold on the ingredient cost reported on the prescription drug event (PDE). We also propose to maintain a specialty-tier cost threshold for both specialty tiers that is set at level that, in general, reflects drugs with monthly ingredient costs that are in the top one percent, as described further in section V.F.6. of this proposed rule. Finally, we propose to adjust the threshold, in an increment of not less than ten percent, rounded to the nearest $10, when an annual analysis of PDE data shows that an adjustment is necessary to recalibrate the threshold so that it only reflects drugs with the top one percent of monthly ingredient costs. We propose to determine annually whether the adjustment would be triggered and announce the specialty-tier cost threshold annually.

j. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

This rule proposes to require that Part D plan sponsors implement, no later than January 1, 2022, a beneficiary real-time benefit tool (RTBT). This tool would allow enrollees to view a plan-defined subset of the information included in the prescriber RTBT system, which will include accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives and utilization management requirements). Plans would be permitted to use existing secure patient portals to fulfill this requirement, to develop a new portal, or use a computer application. Plans would be required to make this information available to enrollees who call the plans' customer service call center.

In order to encourage enrollees to use the beneficiary RTBT, we propose to allow plans to offer rewards and incentives (RI) to their enrollees who log onto the beneficiary RTBT or seek to access this information via the plan's customer service call center.

k. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)

We are proposing to amend the MA medical loss ratio (MLR) regulation at § 422.2420 so that the incurred claims portion of the MLR numerator includes all amounts that an MA organization pays (including under capitation contracts) for covered services. Currently, incurred claims in the MLR numerator include direct claims paid to providers for covered services furnished to all enrollees under an MA contract. This proposal would include in the incurred claims portion of the MLR numerator amounts paid for covered services to individuals or entities that do not meet the definition of ''provider'' as defined at § 422.2.

We are also proposing to codify in the regulations at §§ 422.2440 and 423.2440 the definitions of partial, full, and non-credibility and the credibility factors that CMS published in the Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Final Rule (78 FR 31284) (hereinafter referred to as the May 2013 Medicare MLR final rule). We believe that it is more consistent with the policy and principles articulated in Executive Order 13892 on Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication (October 9, 2019) that we define and publish the definitions of partial, full, and non-credibility and the credibility factors in the **Federal Register**, and that we codify these definitions and factors in the Code of Federal Regulations, as opposed to using the annual Advance Notice and Rate Announcement process, as specified in current §§ 422.2440 and 423.2440.

Additionally, we are proposing to amend § 422.2440 to provide for the application of a deductible factor to the

MLR calculation for MA medical savings account (MSA) contracts that receive a credibility adjustment. The proposed deductible factor would serve as a multiplier on the applicable credibility adjustment. This additional adjustment for MA MSAs is intended to recognize that the variability of claims experience is greater under health insurance policies with higher deductibles than under policies with lower deductibles, with high cost or outlier claims representing a larger portion of the overall claims experience of plans with high deductibles. The proposed deductible factor would reduce the risk that an MSA contract will fail to meet the MLR requirement as a result of random variations in claims experience. We are proposing to adopt the same deductible factors that apply under the commercial MLR regulations at 45 CFR part 158.

l. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)

We are proposing to strengthen network adequacy rules for MA plans by codifying our existing network adequacy methodology and standards (with some modifications); we are also seeking comment on refining standards related to telehealth, maximum time and distance standards, and whether there are additional changes we should consider to improve MA plan access in all county types, such as to address the effect of Certificate of Need (CON) requirements, or whether there more specific changes we should consider to increase plan choice in more rural counties. The authorization of additional telehealth benefits pursuant to the BBA of 2018 incentivizes new ways for beneficiaries to access health care beginning in 2020. As a result, CMS has been examining its network adequacy standards overall to determine how contracted telehealth providers should be considered when evaluating the adequacy of an MA plan network. We propose to allow MA plans to receive a 10 percent credit towards the percentage of beneficiaries residing within published time and distance standards when they contract with telehealth providers in the following provider specialty types: dermatology, psychiatry, cardiology, otolaryngology and neurology. We also are soliciting comment regarding whether we should expand this credit to other specialty provider types, such as nephrology for home dialysis and if this percentage ''credit'' should vary by county type.

Additionally, in order to expand access to MA plans where network development can be challenging, we propose to modify the current network adequacy standards by codifying a reduced standard for the percentage of beneficiaries that must reside within the maximum time and distance standards in non-urban counties (Micro, Rural, and Counties with Extreme Access Considerations (CEAC) county type designations) for an MA plan to comply with the network adequacy standards. We also solicit comment about whether and how much of a percentage reduction would likely be required to incentivize MA penetration and whether the reduction should apply to all county types, or just non-urban counties.

m. Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38)

Sections 1851(e)(4) and 1860D–1(b)(3) of the Act establish special election periods (SEPs) during which, if certain circumstances exist, an individual may request enrollment in, or disenrollment from, MA and Part D plans. The Secretary also has the authority to create SEPs for individuals who meet other exceptional conditions. We are proposing to codify a number of SEPs that we have adopted and implemented through subregulatory guidance as exceptional circumstances SEPs. Codifying our current policy for these SEPs will provide transparency and stability to the MA and Part D programs by ensuring that the SEPs are known and changed only through additional rulemaking. Among the proposed SEPs are the SEP for Individuals Affected by a FEMA-Declared Weather-Related Emergency or Major Disaster, the SEP for Employer/Union Group Health Plan (EGHP) elections, and the SEP for Individuals Who Disenroll in Connection with a CMS Sanction. We are also proposing to establish two additional SEPs for exceptional circumstances: the SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer.

n. Service Delivery Request Processes Under PACE (§§ 460.104 and 460.121)

Currently, PACE participants or their designated representatives may request to initiate, eliminate or continue a service, and in response, the PACE organization must process this request under the requirements at § 460.104(d)(2). These requests are commonly referred to by CMS and the industry as ''service delivery requests.'' In response to feedback from PACE organizations and advocacy groups, and based on our experience monitoring PACE organizations' compliance with our current requirements, we are proposing to move the requirements for processing service delivery requests from § 460.104(d)(2) and add them to a new § 460.121 in order to increase transparency for participants and reduce confusion for PACE organizations. We are also proposing to modify these provisions in order to reduce unnecessary burden on PACE organizations and eliminate unnecessary barriers for participants who have requested services that a PACE organization would be able to immediately approve. Specifically, we are proposing to more clearly define what constitutes a service delivery request, and provide transparent requirements for how those requests would be processed by the PACE organization, including who can make a request, how a request can be made, and the timeframe for processing a service delivery request. We are also proposing to allow the interdisciplinary team (IDT) to bypass the full processing of a service delivery request under the new proposed requirements under § 460.121 when the request can be approved in full by an IDT member at the time it is made. For all other service delivery requests that are brought to the IDT, we are proposing to maintain the requirement that an in-person reassessment must be conducted prior to a service delivery request being denied, but we are proposing to eliminate the requirement that a reassessment (either in-person or through remote technology) be conducted when a service delivery request can be approved. Lastly, we are proposing to add participant protections; specifically, we are proposing to increase notification requirements in order to ensure participants understand why their request was denied, and we are proposing to add reassessment criteria in order to ensure reassessments are meaningful to the service delivery request, and that the IDT takes them into consideration when rendering a decision.

o. Beneficiaries With Sickle Cell Disease (SCD) (§ 423.100)

Beneficiaries with active cancer-related pain, residing in a long-term care facility, or receiving hospice, palliative, or end-of-life care currently meet the definition of ''exempt individuals'' with respect to DMPs in § 423.100. Section 1860D–4(c)(5)(C)(ii)(III) of the Act provides the Secretary with the authority to elect to treat other beneficiaries as exempted from DMPs.

Due to concerns of misapplication of opioid restrictions in the sickle cell disease (SCD) patient population, CMS is proposing that, starting in plan year 2021, beneficiaries with SCD are classified as exempt individuals.

3. Summary of Costs and Benefits

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Provision	Description	Impact
a. Mandatory Drug Management Programs (DMPs) (§ 423.153)	This provision would codify the SUPPORT Act requirement making it mandatory that Part D sponsors implement DMPs, starting in plan year 2022.	There are costs of about $0.1 million a year with a 10-year total cost of $0.8 million.
b. Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)	This provision would require that CMS identify beneficiaries enrolled in Medicare Part D with a history of opioid-related overdose (as defined by the Secretary) and include such individuals as PARBs for prescription drug abuse under sponsors' DMPs.	Part D enrollees with a history of opioid-related overdose have higher than average drug costs. CMS estimates that Part D DMPs could save 5 percent in costs per year. After the first year, the reduction in drug utilization would result in an annual savings of $7.7 million to the Medicare Trust Fund resulting from reduced drug spending by beneficiaries. The costs for case management and related paperwork is estimated at $10.1 million annually after the first year.
c. Automatic Escalation to External Review under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries (§§ 423.153, 423.590, and 423.600)	CMS is proposing that if a Part D sponsor denies a DMP appeal, the case shall be automatically forwarded to the independent outside entity for review and resolution. We are proposing that a plan sponsor must forward the case to the independent outside entity by the expiration of the adjudication timeframe applicable to the plan level appeal. Finally, we are proposing conforming revisions to the notices that are sent to beneficiaries.	We estimate there will be about 28,600 appeals per year, of which 0.08 percent will be denied and automatically escalated to the independent review entity (IRE). Therefore, there are only about 23 cases (0.08 percent * 28,600) affected by this provision. Since most IRE cases are judged by a physician at a wage of $202.46, and typically an IRE will take at most 1 hour to review, the total burden is negligible (about $4,656.58 (23 cases * $202.46 * 1 hour)).

d. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)	CMS is proposing to implement two sections of the SUPPORT Act, which will-- (1) require Part D plan sponsors to notify the Secretary of the imposition of a payment suspension on pharmacies that is based on a credible allegation of fraud, impose such payment suspensions consistent with the manner in which CMS implements payment suspensions in fee-for service Medicare, and report such information using a secure website portal; (2) define inappropriate prescribing with respect to opioids; (3) require plan sponsors to submit to the Secretary information on investigations and other actions related to inappropriate opioid prescribing; (4) define "substantiated or suspicious activities" related to fraud, waste, or abuse; and (5) establish a secure portal which would enable the sharing of data and referrals of "substantiated or suspicious activities" related to fraud, waste, or abuse among plan sponsors, CMS, and CMS's program integrity contractors..	While we believe there may be savings generated through actions taken by plans that will conduct their own due diligence from the reporting and sharing of administrative actions between CMS and plans sponsors, as well as additional law enforcement actions, we cannot estimate the impact at this time. The reporting requirements will cost about $9.5 million a year after the first year.
e. Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)	CMS is proposing to codify requirements under section 17006 of the Cures Act. Effective for the plan year beginning January 1, 2021, CMS proposes to remove the prohibition for beneficiaries with ESRD from enrolling in an MA plan.	Since there are no new provisions regarding enrollment of beneficiaries with ESRD, or kidney acquisition costs, in this regulation that are not in the Act; there are no impacts to report as resulting solely from this provision.
f. Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries (§ 422.322)	CMS is proposing to codify requirements under section 17006 of the Cures Act. Effective for the plan year beginning January 1, 2021, CMS proposes that MA organizations will no longer be responsible for costs for organ acquisitions for kidney transplants for their beneficiaries. Instead, CMS proposes to require that Medicare FFS cover the kidney acquisition costs for MA beneficiaries, effective 2021.	To estimate the impact, we used a pre-statute baseline. This analysis shows that FFS coverage of kidney acquisition costs for MA beneficiaries results in net costs to the Medicare Trust Funds ranging from $212 million in 2021 to $981 million in 2030.
g. Exclusion of Kidney Acquisition Costs from Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306)	CMS is proposing to codify requirements under section 17006 of the Cures Act. Effective for the plan year beginning January 1, 2021, CMS proposes to remove costs for organ acquisitions for kidney transplants from the calculation of MA benchmarks and annual capitation rates.	To estimate the impact, we used a pre-statute baseline. This analysis shows that excluding kidney acquisition costs from MA benchmarks results in net savings estimated to range from $594 million in 2021 to $1,346 million in 2030.

h. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)	We are proposing routine measure updates and an increase in the weight of patient experience/complaints and access measures. We are also proposing some technical clarifications of the current rules for the QBP ratings methodology. We also propose the use of Tukey outlier deletion, which is a standard statistical methodology for removing outliers, to increase the stability and predictability of the star measure cut points.	Updating the patient experience/complaints and access measures weight would create a cost which is offset by using the Tukey outlier deletion. The net savings to the Medicare Trust Fund is $368.1 million in 2024; this will grow over time reaching $999.4 million by 2030. The net reduction in spending to the Medicare Trust Fund over 10 years is $4.9 billion.
i. Permitting a Second, "Preferred", Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)	CMS is proposing to (1) allow Part D sponsors to establish a second, "preferred," specialty tier at a lower cost-sharing threshold than the current specialty tier; (2) codify the existing maximum cost sharing for the highest specialty tier; (3) codify a methodology to determine annually the specialty tier cost threshold using ingredient cost and increase the threshold when certain conditions are met; (4) require sponsors to permit tiering exceptions between the two specialty tiers; and (5) permit sponsors to determine which drugs go on either tier.	Permitting Part D sponsors to establish a second, "preferred", specialty tier is unlikely to have a material impact on Part D costs.
j. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)	CMS is proposing to require that each Part D plan implement a beneficiary real time benefit tool. This tool should allow enrollees to view a plan-defined subset of the information included in the prescriber RTBT system which includes accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives and utilization management requirements) by January 1, 2022.	Adoption of a beneficiary RTBT will be an additional cost and burden on Part D sponsors. Based on our estimates, we believe this will cost Part D plans about $3.9 million for all plans in the first year based on the costs for them to reprogram their computer systems. Additionally, the voluntary provision of rewards by Part D sponsors to enrollees using RTBT will have an impact of $0.7 million in the first year, in order to implement the program, and $0.4 million in subsequent years in order to maintain the program.

k. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)	We are proposing to amend our MA MLR regulations. There are three proposals. (1) We are proposing to allow MA organizations to include in the MLR numerator as "incurred claims" all amounts paid for covered services, including amounts paid to individuals or entities that do not meet the definition of "provider" as defined at § 422.2. (2) We are also proposing to codify our definitions of partial, full, and non-credibility and credibility factors that CMS published in the May 2013 Medicare MLR final rule (78 FR 31296). (3) For MA MSA contracts receiving a credibility adjustment, we are proposing to apply a deductible factor to the MLR calculation in order to recognize that the variability of claims experience is greater under health insurance policies with higher deductibles than under policies with lower deductibles.	(1) Our proposed amendment to change the type of expenditures that can be included in "incurred claims" will have neutral dollar impact on the Medicare Trust Fund. These provisions will result in a transfer of funds from the Treasury, through the Medicare Trust Fund, to MA organizations. This transfer would take the form of a reduction in the remittance amounts withheld from MA capitated payments. The amount of this transfer is $35 to $55 million a year, resulting in plans obtaining $455 million over 10 years. (2) Codifying the definitions of partial, full, and non-credibility and the credibility factors, as proposed, is unlikely to have any impact on the Medicare Trust Fund. (3) Our proposal to add a deductible factor to the MLR calculation for MA MSA contracts is estimated to result in a gradually increasing cost to the Medicare Trust Fund of $1 to $6 million per year, and will result in a $43.2 million cost over 10 years.
l. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)	CMS is proposing to (1) strengthen network adequacy rules for MA and cost plans and make them more transparent to plans by codifying our existing network adequacy methodology and standards, with some modifications; (2) allow MA plans to receive a 10 percent credit towards the percentage of beneficiaries residing within published time and distance standards when they contract with certain telehealth providers; and (3) reduce the required percentage of beneficiaries residing within maximum time and distance standards in certain county types (Micro, Rural, and CEAC).	Changes to network standards are unlikely to have any impact on the Medicare Trust Fund.

m. Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38)	We are proposing to codify a number of SEPs that we have adopted and implemented through subregulatory guidance as exceptional circumstances SEPs. We are also proposing to establish two new SEPs for exceptional circumstances: the SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer.	This provision codifies existing practice since MA organizations and Part D plan sponsors are currently assessing applicants' eligibility for election periods as part of existing enrollment processes. Consequently, the provision will not have added impact.
n. Service Delivery Request Processes under PACE (§§ 460.104 and 460.121)	CMS is proposing to revise the process by which PACE organizations address service delivery requests. Currently the IDT must determine the appropriate member(s) of the IDT to conduct a reassessment, perform a reassessment, and render a decision on each service delivery request. However, our experience shows that approximately 40 percent of all requests could be immediately approved in full by an IDT member. We are therefore removing the obligation for a request to be brought to the IDT or for a reassessment to be conducted when a member of the IDT receives and can approve a service delivery request in full at the time it is made. We are also proposing to remove the requirement to conduct a reassessment in response to a service delivery request except when a request would be partially or fully denied.	The proposed revisions create efficiencies which are estimated to create cost savings of $18.7 million in the first year and gradually increase to $23.9 million in 2030. The net savings over 10 years is $216.3 million dollars. The savings are true savings to PACE organizations as a result of reduced administrative burden.
o. Beneficiaries with Sickle Cell Disease (SCD) (§ 423.100)	CMS is proposing that beneficiaries with SCD are classified as exempted from DMPs starting in plan year 2021.	We estimate this provision will affect under 70 beneficiaries and therefore the impact is negligible.

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II. Implementation of Certain Provisions of the Bipartisan Budget Act of 2018

A. Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102)

The BBA of 2018 (Pub. L. 115–123) was signed into law on February 9, 2018. The law included new authorities concerning supplemental benefits that may be offered to chronically ill enrollees in Medicare Advantage (MA) plans, specifically amending section 1852(a)(3) of the Act to add a new subparagraph (D) authorizing a new category of supplemental benefits that may be offered by MA plans. We discussed this new authority in the April 2018 final rule (83 FR 16481 through 16483).[2] We propose to codify the existing guidance (April 2019 Health Plan Management System (HPMS) Memo [3] and the 2020 Call Letter) [4] and parameters for these special supplemental benefits for chronically ill enrollees at § 422.102(f) to implement section 1852(a)(3)(D) of the Act.

Specifically, the BBA of 2018 amended section 1852(a)(3) of the Act to: (1) Authorize MA plans to provide additional supplemental benefits that have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee to chronically ill enrollees; (2) permit those additional supplemental benefits to be not primarily health related; (3) define ''chronically ill enrollee'' to limit eligibility for these additional supplemental benefits; and (4) authorize CMS to waive uniformity requirements in connection with this for eligible chronically ill enrollees. We refer to these benefits hereafter as Special Supplemental Benefits for the Chronically Ill (SSBCI). The heading for new subparagraph (D) of section 1852(a)(3) of the Act, as added by the BBA, states, ''Expanding supplemental benefits to meet the needs of chronically ill enrollees.'' Consistent with this text, this new category of supplemental benefits is intended to enable MA plans to better tailor benefit offerings, address gaps in care, and improve health outcomes for the chronically ill population. Section 1852(a)(3)(D)(ii) of the Act, as amended, defines a chronically ill enrollee as an individual who—

- Has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee;
- Has a high risk of hospitalization or other adverse health outcomes; and
- Requires intensive care coordination.

Thus, with respect to SSBCI benefits, we propose at § 422.102(f)(1)(i), to codify this definition of a chronically ill enrollee. Section 1859(f)(9) of the Act requires us to convene a panel of

[2] *https://www.govinfo.gov/content/pkg/FR-2018-04-16/pdf/2018-07179.pdf.*

[3] *https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/Supplemental_Benefits_Chronically_Ill_HPMS_042419.pdf.*

[4] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

clinical advisors to establish and update a list of conditions that meet the definition of a severe or disabling chronic condition under section 1859(b)(6)(B)(iii) of the Act, which provides how having such a condition is an eligibility criterion for a chronic care special needs plan. The standard for severe or disabling chronic condition under section 1859(b)(6)(B)(iii) of the Act is substantially similar to the criterion used in defining ''chronically ill enrollee'' for purposes of SSBCI eligibility. Under our proposal, MA plans may consider any enrollee with a condition identified on this list to meet the statutory criterion of having one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee. Further, an MA plan may consider any chronic condition not identified on this list if that condition is life threatening or significantly limits the overall health or function of the enrollee. CMS wishes to allow plans the flexibility to continue to innovate around providing care for their specific plan populations. This includes targeted chronic conditions. We recognize that there may be some conditions and/or a subset of conditions in a plan population that may meet the statutory definition of a chronic condition, but may not be present on the list. We encourage plans to identify needs within their unique plan population and do not wish to prevent a plan from addressing a condition or need in their population that may not be on the list. To reflect this policy, we are proposing at § 422.102(f)(1)(i)(B), regulation text indicating our intent to publish a non-exhaustive list of medically complex chronic conditions as determined by the panel as described in section 1859(b)(6)(B)(iii) to be life threatening or significantly limit the overall health or function of an individual.

MA plans are not required to submit to CMS the processes used to identify chronically ill enrollees that meet the three pronged definition of chronically ill enrollee. However, all three criteria must be met for an enrollee to be eligible for the SSBCI authorized under section 1852(a)(3)(D) of the Act. In subregulatory guidance (April 2019 HPMS Memo and the 2020 Call Letter), CMS noted that we expect MA plans to document their determinations about an enrollee's eligibility for SSBCI based on the statutory definition. We propose to codify this as a requirement at § 422.102(f)(3)(ii). In addition, we are also proposing at § 422.102(f)(3)(ii) to require plans to make information and documentation (for example, copies of the internal policies used to make the determinations, etc.) related to determining enrollee eligibility as a chronically ill enrollee available to CMS upon request.

We are proposing at paragraph (f)(1)(ii) the definition of SSBCI. In addition to limiting the class of enrollees who may be eligible to receive the new SSBCI benefits to the chronically ill, section 1852(a)(3)(D) of the Act requires that the specific supplemental benefit provided under this authority have a reasonable expectation of improving or maintaining the health or overall function of the enrollee. We propose to codify this statutory requirement as part of the definition of SSBCI at § 422.102(f)(1)(ii). Because SSBCI are supplemental benefits, they must also comply with the criteria for supplemental benefits that we are proposing to codify at § 422.100(c)(2)(ii), which is discussed in detail in section VI.F. of this proposed rule. We considered whether the regulation for SSBCI should explicitly reference the requirements in § 422.100(c)(2)(ii) to make this clear and solicit comment on this point. Traditionally, CMS has defined supplemental benefits as benefits that: (1) Are primarily health related; (2) require the MA plan to incur a non-zero medical cost; and (3) are not covered under Medicare Parts A, B or D. In light of the authority in section 1852(a)(3)(D) of the Act for SSBCI, we are proposing to modify some aspects of this longstanding policy in this context. First, as the statute provides that SSBCI may be not primarily health related, we are proposing specific text on this point in both §§ 422.100(c)(2)(ii) and 422.102(f)(1)(ii). Second, we are proposing to clarify in § 422.100(c)(2)(ii)(B) that the MA organization incur a non-zero direct medical cost for all supplemental benefits applies in the context of SSBCI that are not primarily health related; in such cases, the MA organization must incur a non-zero direct non-administrative cost for the SSBCI. MA rules require plans to incur a non-zero direct medical cost for supplemental benefits. In the case of SSBCI, we are clarifying that such incurred cost should be a non-administrative cost for providing the benefit even if it is not necessarily a cost paid to a medical provider or facility because SSBCI benefits are not necessarily primarily health related. In all other respects not specifically addressed as part of our proposal, SSBCI would be treated like other supplemental benefits.

Under section 1852(a)(3)(D)(ii)(I) of the Act, SSBCI benefits may include items or services that are not primarily health related. As discussed in detail in section VI.F. of this proposed rule, a primarily health related benefit is an item or service that is used to diagnose, compensate for physical impairments, acts to ameliorate the functional/psychological impact of injuries or health conditions, or reduces avoidable emergency and healthcare utilization. Therefore, at § 422.102(f)(1)(ii), we propose to codify as part of the definition of SSBCI that these benefits may be non-primarily health related SSBCI benefits, including a cross-reference to where we propose to codify the definition of primarily health related; however, in all cases, an SSBCI must have, with respect to a chronically ill enrollee, a reasonable expectation of improving or maintaining the health or overall function of the enrollee. By including it in the definition, we are implementing the statutory authority for MA plans to offer both primarily health and non-primarily health related SSBCI. In the 2019 HPMS memo, we provided examples of non-primarily health related SSBCI benefits. Those examples included: Meals (beyond a limited basis), food and produce, transportation for non-medical needs, pest control, indoor air quality and equipment and services, access to community or plan-sponsored programs and events to address enrollee social needs, (such as non-fitness club memberships, community or social clubs, park passes, etc.), complementary therapies (offered alongside traditional medical treatment), services supporting self-direction (for example. financial literacy classes, technology education, and language classes), structural home modifications, and general supports for living (for example. plan-sponsored housing consultations and/or subsidies for rent or assisted living communities or subsidies for utilities such as gas, electric, and water). We intend this guidance to be equally applicable to our proposed regulation.

Another provision of our proposed rule flows from the statutory authority for SSBCI to be not primarily health related. Unlike with traditional supplemental benefits, MA plans might not incur direct medical costs in furnishing or covering SSBCI. In the 2020 Call Letter, we issued guidance that so long as an MA plan incurs a non-zero non-administrative cost in connection with SSBCI, the benefits would be considered to meet this standard. As supplemental benefits, SSBCI may also take the same form as

traditional supplemental benefits. For example, reductions in cost sharing for benefits under the original Medicare fee-for-service program are an allowable supplemental benefit, as reflected in the definitions of mandatory supplemental benefit in § 422.2. Thus, SSBCI can be in the form of—

- Reduced cost sharing for Medicare covered benefits (such as to improve utilization of high-value services that meet the definition of SSBCI);
- Reduced cost sharing for primarily health related supplemental benefits;
- Additional primarily health related supplemental benefits; or
- Additional non-primarily health related supplemental benefits.

Eligibility for SSBCI must be determined based on identifying the enrollee as a chronically ill enrollee, using the statutory definition, and if the item or service has a reasonable expectation of improving or maintaining the health or overall function of the enrollee. In the April 2019 HPMS memo CMS clarified that MA plans can provide non-primarily health related supplemental benefits that address chronically ill enrollees' social determinants of health so long as the benefits maintain or improve the health or function of that chronically ill enrollee. MA plans may consider social determinants when determining eligibility for an SSBCI of health as a factor to help identify chronically ill enrollees whose health could be improved or maintained with SSBCI. However, MA plans may not use social determinants of health as the sole basis for determining eligibility for SSBCI. We propose to codify the ability of an MA plan to consider social determinants (for example, food and housing insecurity) when determining whether an SSBCI benefit is likely to improve or maintain the health of a chronically ill enrollee as described at § 422.102(f)(2)(iii).

Generally, § 422.100(d) and other regulations require all MA plan benefits to be offered uniformly to all enrollees residing in the service area of the plan. As explained in the April 2018 final rule (83 FR 16480 through 16485), MA plans may also provide access to services (or specific cost sharing or deductibles for specific benefits) that are tied to a disease state in a manner that ensures that similarly situated individuals are treated uniformly. Section 1852(a)(3)(D)(ii)(II) of the Act authorizes CMS to waive the uniformity requirements generally applicable to benefits covered by MA plans with respect to SSBCI, effective in CY 2020. As discussed in the April 2018 final rule (83 FR 16481 and 16482), this gives CMS the authority to allow MA plans to offer chronically ill enrollees supplemental benefits that are not uniform across the entire population of chronically ill enrollees in the MA plan and may vary SSBCI offered to the chronically ill as a specific SSBCI relates to the individual enrollee's specific medical condition and needs. We are proposing to codify the authority for this waiver at § 422.102(f)(2)(ii) such that upon approval by CMS, an MA plan may offer non-uniform SSBCI. In both the CY 2020 call letter and the April 2019 HPMS memo, we explained how we expect MA plans to have written policies based on objective criteria (for example, health risk assessments, review of claims data, etc.) for determining SSBCI eligibility to receive a particular SSBCI benefit, to document these criteria, and to make this information available to CMS upon request. We are also proposing to codify requirements at § 422.102(f)(3)(iii) and (iv) for MA plans that offer SSBCI to have written policies based on objective criteria, document those criteria, to document each determination that an enrollee is eligible to receive an SSBCI and make this information available to CMS upon request. We believe that objective criteria are necessary to address potential beneficiary appeals, complaints, and/or general oversight activities performed by CMS. We are also proposing, at § 422.102(f)(3)(i), to require plans to have written policies for determining enrollee eligibility and must document its determination that an enrollee is a chronically ill enrollee based on the statutory definition codified in paragraph (f)(1)(i) of this section. And we are proposing to require plans to make information and documentation related to determining enrollee eligibility available to CMS upon request at § 422.102(f)(3)(ii). We also clarify here that the determination on the benefits an enrollee is entitled to receive under an MA plan's SSBCI is an organization determination that is subject to the requirements of part 422, subpart M, including the issuance of denial notices to enrollees.

This provision codifies already existing guidance and practices and therefore is not expected to have additional impact above current operating expenses. Additionally, this provision amends definitions and therefore does not impose any collection of information requirements.

B. Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§ 422.101)

Special needs plans (SNPs) are MA plans that are specifically designed to provide targeted care and limit enrollment to special needs individuals. Section 50311 of the BBA of 2018 modified the requirements for C–SNPs in section 1859(f)(5) of the Act. Specifically, the amendments included the following:

- That the interdisciplinary team include a team of providers with demonstrated expertise, including training in an applicable specialty, in treating individuals similar to the targeted population of the C–SNP.
- That the C–SNP comply with requirements developed by CMS to provide face-to-face encounters with enrollees not less frequently than on an annual basis.
- That, as part of the mandatory model of care (MOC), the results of the initial assessment and annual reassessment required for each enrollee be addressed in the individual's individualized care plan.
- That, as part of the annual evaluation and approval of the MOC, CMS take into account whether the plan fulfilled the previous year's goals (as required under the model of care).
- That CMS establish a minimum benchmark for each element of the MOC and only approve a C–SNP's MOC if each element of the model of care meets such minimum benchmark applicable under the preceding sentence.

We are proposing to amend and add new regulations at § 422.101(f) to implement the BBA of 2018 amendments to section 1859(f) of the Act and extend them to all SNP types. Specifically, we propose to add new regulations, to be codified at § 422.101(f), to account for two new requirements governing SNP enrollee care management and three new requirements governing SNP model of care submissions.

The history of special needs plans in the MA program is nearly as long as the program itself. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (hereinafter referred to as the MMA) (Pub. L. 108–173) authorized CMS to contract with MA coordinated care plans that are specifically designed to provide targeted care to individuals with special needs. Originally SNPs were statutorily authorized for a limited period, but after several extensions of that authority, section 50311(a) of the BBA of 2018 permanently authorized SNPs. Under section 1859(f)(1) of the Act, SNPs are able to restrict enrollment to Medicare beneficiaries who are: (1) Institutionalized individuals, who are currently defined in § 422.2 as those residing or expecting to reside for 90 days or longer in a long-term care facility; (2) individuals entitled to

medical assistance under a state plan under Title XIX; or (3) other individuals with certain severe or disabling chronic conditions who would benefit from enrollment in a SNP. As of July 2019, 321 SNP contracts with 734 SNP plans have at least 11 members.[5] These figures included 208 Dual Eligible SNP contracts (D–SNPs) with 480 D–SNP plans with at least 11 members, 57 Institutional SNP contracts (I–SNPs) with 125 I–SNP plans with at least 11 members, and 56 Chronic or Disabling Condition SNP contracts (C–SNPs) with 129 C–SNP plans with at least 11 members. For more discussion of the history of SNPs, please see Chapter 16b of the Medicare Managed Care Manual (MMCM).[6] This proposed rule would implement the provisions of the BBA of 2018 and establish new care management requirements at § 422.101(f) for all SNPs, including minimum benchmarks for SNP models of care.

Section 1859(f) of the Act and the current implementing regulations specify several requirements for SNPs. MA organizations that would like to offer a SNP are required to engage in an application process to demonstrate that they meet SNP specific requirements, including the requirement in § 422.101(f) that MA organizations offering a SNP implement an evidence based model of care (MOC) to be evaluated by the National Committee for Quality Assurance (NCQA); the requirement in § 422.107 that D–SNPs have a contract with the state Medicaid agencies in the states in which they operate; and the requirement in § 422.152(g) that SNPs conduct quality improvement programs. SNP applicants follow the same process in accordance with the same timeline as applicants seeking to contract to offer other MA plans.

Section 164 of the Medicare Improvements for Patients and Providers Act (hereinafter referred to as MIPPA) (Pub. L. 110–275) added care management requirements for all SNPs effective January 1, 2010, as set forth in section 1859(f)(5) of the Act (42 U.S.C. 1395w–28(f)). The new mandate required dual-eligible, institutional, and chronic condition SNPs to implement care management requirements which have two explicit components: An evidence-based model of care and a series of care management services. While the revisions made in the Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs interim final rule with comment (73 FR 54226), hereinafter referred to as the September 2008 final rule, simply reflected the substance of the new MIPPA provisions, the Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs proposed rule, hereinafter referred to as the May 2008 proposed rule (73 FR 28555), proposed other, related provisions which were finalized in the Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions final rule (hereinafter referred to as the January 2009 final rule) (74 FR 1493).

CMS had previously provided guidance and instructions in the 2008 and 2009 Call Letters,[7] [8] ''Special Needs Plan Solicitation,'' in order to more clearly establish and clarify delivery of care standards for SNPs and to codify standards. In the May 2008 proposed rule, CMS proposed that SNPs have networks with clinical expertise specific to the special needs population of the plan; use performance measures to evaluate models of care; and be able to coordinate and deliver care targeted to the frail/disabled, and those near the end of life based on appropriate protocols. Section 164 of the MIPPA subsequently added care management requirements for all SNPs as directed in section 1859(f)(5) of the Act (42 U.S.C. 1395w–28(f)), outlining new model of care requirements that include—(1) an appropriate network of providers and specialists to meet the specialized needs of the SNP target population; (2) a comprehensive initial health risk assessment and annual reassessments; (3) an individualized plan of care having goals and measurable outcomes; and (4) an interdisciplinary team to manage care. The MIPPA laid a statutory foundation for much of our regulatory standards for the model of care.

MOCs are a vital quality improvement tool and integral component for ensuring that the unique needs of each beneficiary enrolled in a SNP are identified and addressed. Section 3205 of the Patient Protection and Affordable Care Act of 2010 (hereinafter referred to as the Affordable Care Act) (Pub. L. 111–148) amended section 1859(f) of the Act to require that, starting in 2012, all SNPs be approved by NCQA based on standards developed by the Secretary. As provided under §§ 422.4(a)(iv), 422.101(f), and 422.152(g), the NCQA approval process is based on evaluation and approval of the SNP MOC, as per CMS guidance. Therefore, all SNPs must submit their MOCs to CMS for NCQA evaluation.

The MOC is organized to promote clarity and enhance the focus on care coordination, care transition, care needs and activities. The NCQA scoring approval process is based on scoring each of the clinical and non-clinical elements of the MOC as part of the SNP application.

The MOC narrative must include the following four elements:

- Description of the SNP Population.
- Care Coordination.
- SNP Provider Network.
- MOC Quality Measurement & Performance Improvement.

Each of the four elements is comprised of a set of required subcomponents, or factors, such as an identification and comprehensive description of the SNP-specific population. These subcomponents are reviewed and scored by NCQA and contribute to the overall score for that element. A full list of elements and factors, as well as CMS subregulatory guidance pertaining to MOC submission requirements and structure, can be found in Chapter 5 of the MMCM.

We propose to revise § 422.101(f) to implement certain new requirements added to section 1859(f)(5)(B) of the Act by the BBA of 2018 and to extend them to all SNP types. Specifically, we propose to revise § 422.101(f) to impose the new requirements governing SNP enrollee care management and SNP MOC submissions. Section 50311(c) of the BBA of 2018 amends section 1859(f)(5) of the Act to explicitly require improvements in care management and the establishment of a minimum benchmark for each element of the SNP model of care of a plan specific to C–SNP MOC submissions. We are proposing that these requirements be extended to all SNP plan types for several reasons. First, these additional requirements are consistent with current regulations and sub-regulatory guidance CMS provides to all SNPs regarding care management and MOC compliance. Second, we believe that these proposed

[5] See the following link for SNP plan and enrollment data: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data-Items/SNP-Comprehensive-Report-2019-07.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=descending.*

[6] Chapter 16b of the Medicare Managed Care Manual can be found at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c16b.pdf.*

[7] Announcement of Calendar Year (CY) 2008 Medicare Advantage Capitation Rates and Payment Policies can be found at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/announcement2008.pdf.*

[8] Announcement of Calendar Year (CY) 2009 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies can be found at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2009.pdf.*

regulations are important safeguards to preserve the quality of care for all special needs individuals, including those enrolled in D–SNPs and I–SNPs and not just those enrolled in C–SNPs. Given the prevalence of medically complex chronic conditions among I–SNP and D–SNP enrollees, we believe the proper application of these new care improvement requirements would improve care for enrollees with complex chronic conditions. Further, we believe that the application of multiple, different MOC standards would be operationally complex and burdensome for MA organizations that sponsor multiple SNP plan types, for instance, a D–SNP and a C–SNP. We welcome comment of the extension of the new care management and MOC requirements for C–SNPs to the care management and MOC requirements for all SNP types.

1. The Interdisciplinary Team in the Management of Care

First, we propose to implement the requirement in section 1859(f)(5)(B)(i) of the Act addressing the interdisciplinary team in an amendment to § 422.101(f)(1)(iii) that would, in addition to implementing the statutory requirement for C–SNPs, extend the requirement to all SNPs. Currently, § 422.101(f)(1)(iii) requires each SNP to use an interdisciplinary team in the management of care but does not include much detail about that requirement. We propose to amend paragraph (f)(1)(iii) to require that each MA organization offering a SNP plan must provide each enrollee with an interdisciplinary team in the management of care that includes a team of providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan.

As we noted in the January 2009 final rule, MIPPA required SNPs to conduct initial and annual comprehensive health risk assessments, develop and implement an individualized plan of care, and implement an interdisciplinary team for each beneficiary. We believe that combination of MIPPA's statutory elements and our regulatory prescription for the SNP model of care establishes the standardized architecture for effective care management while giving plans the flexibility to design the unique services and benefits that enable them to meet the identified needs of their target population. We believe this proposal, which amends paragraph (f)(1)(iii) and applies additional requirements pertaining to demonstrated expertise and training of interdisciplinary team providers to all SNPs, is consistent with the MIPPA requirements and the January 2009 final rule that provided the original authority regarding the use of interdisciplinary teams. All SNPs must have an interdisciplinary team to coordinate the delivery of services and benefits. However, one SNP may choose to contract with an interdisciplinary team to deliver care in community health clinics and another SNP may hire its team to deliver care in the home setting. Under the current rule, and our proposal, all SNPs must coordinate the delivery of services and benefits through integrated systems of communication among plan personnel, providers, and beneficiaries. However, one SNP may coordinate care through a telephonic connection among all stakeholders and a second SNP may coordinate care through an electronic system using Web-based records and electronic mail accessed exclusively by the plan, network providers, and beneficiaries. All SNPs must coordinate the delivery of specialized benefits and services that meet the needs of their most vulnerable beneficiaries. However, D–SNPs may need to coordinate Medicaid services while an institutional SNP may need to facilitate hospice care for its beneficiaries near the end of life. These examples demonstrate the variety of ways SNPs currently implement their systems of care, and we believe plans can and should provide enrollees with a team of providers with expertise and training that are appropriate for each individual enrollee.

Ultimately, we believe plans are in the best position to identify an interdisciplinary team with the appropriate expertise and training necessary to meet the clinical needs for each enrollee based on the medical and behavioral health conditions of their member population. We solicit comment on this proposed implementation of section 1859(f)(5)(B)(i) of the Act. We welcome feedback on how plans can meet the requirements for both demonstrated expertise and training in an applicable specialty.

2. Face-to-Face Annual Encounters

Second, we propose to implement the requirement in section 1859(f)(5)(B)(ii) of the Act requiring compliance with requirements (developed by CMS) to provide a face-to-face encounter with each enrollee. We are proposing that the face-to-face encounter be between each enrollee and a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff on at least an annual basis, beginning within the first 12 months of enrollment, as feasible and with the individual's consent. A face-for-face encounter must be either in person or through a visual, real-time, interactive telehealth encounter. We propose to implement this requirement in a new paragraph (f)(1)(iv) of § 422.101 that would extend the requirement to all SNPs. We propose to require the MA organization to provide an annual face-to-face visit, that is in-person or by remote technology, to occur starting within the first 12 months of enrollment within the plan. For instance, a plan enrolling a beneficiary on October 1 would need to facilitate an in-person meeting by September 30th of the following year. Under our proposal, a visit to or by a member of an individual's interdisciplinary team or the plan's case management and coordination staff that perform clinical functions, such as direct beneficiary care, would meet this requirement. Examples of what these encounters may entail, though not limited to, include a member of an individual's interdisciplinary team or the plan's case management and coordination staff engaging with the enrollee to manage, treat and oversee (or coordinate) their health care, including preventive care included in the individualized care plan (ICP). Additional examples of such activities may include annual wellness visits and/or physicals, health risk assessment (HRA) completion, care plan review, health related education, and care coordination activities, but these are not the only activities that satisfy the proposed regulatory requirement. Encounters may also address any concerns related to physical, mental/behavioral health, and overall health status, including functional status. We anticipate that, consistent with good clinical practice, concerns are addressed and any appropriate referrals, follow-up, and care coordination activities provided or scheduled as necessary as a result of these face-to-face encounters. Plans should implement this requirement in a manner that honors any enrollee's decision not to participate in any qualifying encounter as noted previously.

Consistent with the authority for MA plans to offer additional telehealth benefits, under § 422.135 as finalized in the Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and

Medicaid Managed Care Programs for Years 2020 and 2021 Final Rule (hereinafter referred to as the April 2019 final rule), we are proposing that the face-to-face encounters required for all SNPs under this new rule may include visual, real-time, interactive telehealth encounters. As we noted in the April 2019 final rule, we believe MA additional telehealth benefits will increase access to patient-centered care by giving enrollees more control to determine when, where, and how they access benefits. We are seeking comment on proposed § 422.101(f)(1)(iv) and the suggested criteria for what constitutes a face-to-face encounter.

3. Health Risk Assessments and the SNP Enrollee's Individualized Care Plan

Third, we are proposing to codify the requirement in section 1859(f)(5)(B)(iii) of the Act that, as part of the C–SNP model of care, the results of the initial assessment and annual reassessment required for each enrollee be addressed in the individual's individualized care plan. As with the other provisions in section 1859(f)(5)(B) of the Act, we are proposing to extend this requirement to the model of care for all SNPs in revisions to § 422.101(f)(1)(i). Currently, MA organizations offering SNPs must conduct a comprehensive initial health risk assessment of the individual's physical, psychosocial, and functional needs as well as annual HRA, using a comprehensive risk assessment tool that CMS may review during oversight activities. We propose to revise § 422.101(f)(1)(i) by adding that the MA organization must ensure that results from the initial assessment and annual reassessment conducted for each individual enrolled in the plan are addressed in the individual's individualized care plan required under § 422.101(f)(1)(ii) are addressed in the individual's individualized care plan required under § 422.101(f)(1)(ii).

We believe that the HRA plays a critical role in coordinating the care of SNP enrollees. Section 1859(f)(5)(A) of the Act requires SNPs to conduct initial and annual comprehensive HRA, develop and implement an individualized plan of care, and implement an interdisciplinary team for each beneficiary. As noted in the January 2009 final rule, we believe that the combination of these statutory elements and our regulatory prescription for the SNP model of care establishes the standardized architecture for effective care management. We believe extending the requirement for the individualized care plan to address the results of the initial assessment and annual reassessment care to I–SNPs and D–SNPs, instead of limiting the requirement to C–SNPs, would further increase the effectiveness of the ICP and increase quality outcomes. We welcome comment concerning the amended regulation at § 422.101(f)(1)(i).

4. SNP Fulfillment of the Previous Year's MOC Goals

Fourth, we are proposing to codify the requirement in section 1859(f)(5)(B)(iv) of the Act that the evaluation and approval of the model of care take into account whether the plan fulfilled the previous MOC's goals and to extend this evaluation component to all SNP models of care, rather than limiting it to C–SNPs. We propose a new regulation at § 422.101(f)(3)(ii) that as part of the evaluation and approval of the SNP model of care, NCQA must evaluate whether goals were fulfilled from the previous model of care and plans must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment of the previous MOC's goals. If the SNP model of care did not fulfill the previous MOC's goals, the plan must indicate in the MOC submission how it will achieve or revise the goals for the plan's next MOC. We are also proposing to move an existing regulation at § 422.101(f)(2)(vi) that requires all SNPs must submit their MOC to CMS for NCQA evaluation and approval in accordance with CMS guidance to a new paragraph at § 422.101(f)(3). The proposed paragraph at (f)(3)(i) would contain the same language as § 422.101(f)(2)(vi).

We intend that NCQA would determine whether each SNP, as part of the evaluation and MOC approval process, provided adequate information to evaluate the regulation under § 422.101(f)(3)(ii) as well as whether the SNP met goals from the previous MOC submission. It is implicit in the evaluation of the MOC and the requirement for the SNP to submit relevant information that the information submitted by the SNP must be adequate for NCQA to use to evaluate whether the goals from the prior MOC have been fulfilled. We solicit comment whether more explicit requirements on this point should be part of the regulation text.

The proposed regulation at § 422.101(f)(3)(ii) aligns with our current guidance on the MOC submission and review process regarding SNP fulfillment of goals. Currently, all SNPs are required to identify and clearly define measureable goals and health outcomes as part of their model of care under MOC 4, Element B: Measureable Goals and Health Outcomes for the MOC as defined in Chapter 5 of the MMCM. CMS believes that it is critical for all SNPs to use the results of the quality performance indicators and measures to support ongoing improvement of the MOC, and that all SNPs should continuously assess and evaluate plan quality outcomes. MOC 4, Element B currently contains the following parameters:

- Identify and define the measurable goals and health outcomes used to improve the health care needs of SNP beneficiaries.
- Identify specific beneficiary health outcome measures used to measure overall SNP population health outcomes at the plan level.
- Describe how the SNP establishes methods to assess and track the MOC's impact on SNP beneficiaries' health outcomes.
- Describe the processes and procedures the SNP will use to determine if health outcome goals are met.
- Describe the steps the SNP will take if goals are not met in the expected timeframe.

For SNPs submitting their initial MOC, NCQA will evaluate the information under MOC 4 Element B as the setting of clearly definable and measurable goals and health outcomes in their MOC for the upcoming MOC period of performance. For the following submission year, the plan will be evaluated on whether the measurable goals and health outcomes set in the initial MOC were achieved.

Plans submitting an initial model of care must provide relevant information pertaining to the MOC's goals for review and approval under this paragraph. We propose specific regulation text on this point at § 422.101(f)(3)(ii)(B). We seek comment on the new regulation at § 422.101(f)(3)(ii).

5. Establishing a Minimum Benchmark for Each Element of the SNP Model of Care

Finally, we propose new regulation text at § 422.101(f)(3)(iii) to impose the requirement for benchmarks to be met for a MOC to be approved. Section 1859(f)(5)(B)(v) of the Act requires that the Secretary establish a minimum benchmark for each element of the C–SNP model of care, and that the MOC can only be approved if each element meets a minimum benchmark. We propose in § 422.101(f)(3)(iii) to implement these benchmarks for all SNP models of care. Given that medically complex conditions are found in enrollees across all SNP types and

that implementation to C–SNPs alone would be operationally challenging for plans offering multiple SNP types, we believe it is appropriate to extend this requirement to all SNPs. Each SNP model of care would be evaluated based on a minimum benchmark for each of the four elements. Currently, each subfactor of a MOC element is valued at 0–4 points with the score of each element based on the number of factors met for that specific element; the aggregate total of all possible points across all elements equals 60, which is then converted to percentage scores based on the number of total points received. We propose that each element of the MOC must meet a minimum benchmark of 50 percent of total points as allotted, and a plan's MOC would only be approved if each element of the model of care meets the applicable minimum benchmark.

We welcome comment on the proposed § 422.101(f)(3)(iii). Specifically, we are seeking comment to our proposed benchmark and scoring criteria as they impact the evaluation of SNP models of care.

C. Coverage Gap Discount Program Updates (§§ 423.100 and 423.2305)

We propose to amend our regulations at §§ 423.100 (definition of applicable drug) and 423.2305 (determination of coverage gap discount) to reflect recent changes to the relevant statutory provisions. Sections 53113 and 53116 of the BBA of 2018 amended section 1860D–14A of the Act to (a) increase the coverage gap discount for applicable drugs from 50 to 70 percent of the negotiated price beginning in plan year 2019, and (b) revise the definition of an applicable drug to include biosimilar biological products, also beginning in plan year 2019.

Specifically, section 53116 of the BBA of 2018 revised the definition of ''discounted price,'' meaning the price provided to the beneficiary, in section 1860D–14A(g)(4)(A) of the Act to mean, for a plan year after 2018, 30 percent of the negotiated price. This means that the coverage gap discount is 70 percent, rather than 50 percent. To make our regulations consistent with this change, we propose to amend the definition of ''applicable discount'' in § 423.2305 to provide that, with respect to a plan year after plan year 2018, the applicable discount is 70 percent of the portion of the negotiated price (as defined in § 423.2305) of the applicable drug of a manufacturer that falls within the coverage gap and that remains after such negotiated price is reduced by any supplemental benefits that are available.

Section 53113 of the BBA of 2018 amended section 1860D–14A(g)(2)(A) of the Act to specify that biologic products licensed under subsection (k) (that is, biosimilar and interchangeable biological products) are excluded from the coverage gap discount program only with respect to plan years before 2019. Therefore, we are proposing to revise the definition of applicable drug at § 423.100 to specify that such biological products are excluded only for plan years before 2019. Accordingly, biosimilar products are included in the Discount Program beginning for plan year 2019.

D. Part D Income Related Monthly Adjustment Amount (IRMAA) Calculation Update for Part D Premium Amounts (§ 423.286)

Section 3308 of the Affordable Care Act amended section 1860D–13(a) of the Act and imposed an income-related monthly adjustment amount for Medicare Part D (hereinafter referred to as Part D–IRMAA) for beneficiaries whose modified adjusted gross income (MAGI) exceeds the same income threshold amount tiers established under section 1839(i) of the Act with respect to the Medicare Part B income-related monthly adjustment amount (Part B–IRMAA). The Part D–IRMAA is an amount that a beneficiary pays in addition to the monthly plan premium for Medicare prescription drug coverage under the Part D plan in which the beneficiary is enrolled when the beneficiary's MAGI is above the specified threshold.

The Part D–IRMAA income tiers mirror those established for the Part B–IRMAA. As specified in section 1839(i) of the Act, when the Part B–IRMAA went into effect in 2007, individuals and joint tax filers enrolled in Medicare Part B whose modified adjusted gross income exceeded $80,000 and $160,000, respectively, were assessed the Part B–IRMAA on a sliding scale. As specified in section 1839(i)(5) of the Act, each dollar amount within the income threshold tiers shall be adjusted annually based on the Consumer Price Index (CPI). As a result of the annual adjustment, for calendar year 2010, the income threshold amounts had increased to reflect the four income threshold amount tiers for individuals and joint tax filers whose modified adjusted gross income exceeded $85,000 and $170,000, respectively. (We note that section 3402 of the Affordable Care Act froze the income thresholds for 2011 through 2019 at the level established for 2010.)

Consistent with section 3308 of the Affordable Care Act, the Part D–IRMAA is calculated using the Part D national base beneficiary premium (BBP) and the applicable premium percentage (P) as follows: BBP × [(P − 25.5 percent)/25.5 percent]. The premium percentage used in the calculation will depend on the level of the Part D enrollee's modified adjusted gross income.

Section 3308 of the Affordable Care Act requires CMS to provide the Social Security Administration (SSA) with the national base beneficiary premium amount used to calculate the Part D–IRMAA no later than September 15 of each year, starting in 2010. Also effective in 2010, CMS must provide SSA no later than October 15 of each year, with: (1) The modified adjusted gross income threshold ranges; (2) the applicable percentages established for Part D–IRMAA in accordance with section 1839 of the Act; (3) the corresponding monthly adjustment amounts; and (4) any other information SSA deems necessary to carry out Part D–IRMAA.

To determine a beneficiary's IRMAA, SSA considers the beneficiary's MAGI, together with their tax filing status, to determine the percentage of the: (1) Unsubsidized Medicare Part B premium the beneficiary must pay; and (2) cost of basic Medicare prescription drug coverage that the beneficiary must pay.

Since the implementation of the Part D–IRMAA in 2011, subsequent revisions to the statute have modified the associated income tiers used in IRMAA calculations:

- Section 402 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, revised the income thresholds for the Part B- and Part D–IRMAA income groups such that beneficiaries with incomes greater than $85,000 but not more than $107,000 were required to pay 35 percent of Part B and Part D program costs; beneficiaries with incomes greater than $107,000 but not more than $133,500 would pay 50 percent of Part B and Part D program costs; beneficiaries with incomes greater than $133,500 but not more than $160,000 would pay 65 percent of Part B and Part D program costs; while beneficiaries with incomes greater than $160,000 were required to pay 80 percent of Part B and Part D program costs.
- Section 53114 of the BBA of 2018 revised the MAGI ranges again such that, beginning in 2019, beneficiaries with incomes greater than $500,000 ($750,000 for joint tax filers) are required to pay 85 percent of program costs (an increase from 80 percent).

We are proposing to revise § 423.286(d)(4)(ii) for consistency with the changes made by section 53114 of

the BBA of 2018 and to make other technical changes to ensure that the calculations used in the methodology for updating Part D–IRMAA are described correctly. We propose to remove the language ''the product of the quotient obtained by dividing the applicable premium percentage specified in § 418.2120 (35, 50, 65, or 80 percent) that is based on the level of the Part D enrollee's modified adjusted gross income for the calendar year reduced by 25.5 percent and the base beneficiary premium as determined under paragraph (c) of this section'' and replace it with the product of the standard base beneficiary premium, as determined under paragraph (c) of this section, and the ratio of the applicable premium percentage specified in 20 CFR 418.2120, reduced by 25.5 percent; divided by 25.5 percent (that is, premium percentage − 25.5)/25.5).

We are not scoring this provision in the Regulatory Impact Analysis section since it codifies existing guidance. We believe all stakeholders are already following the current guidance. We are also not scoring this provision in the Collection of Information section since we believe all information impacts of this provision have already been accounted for under OMB control number 0938–0964 (CMS–10141), but seek comment on this assumption.

E. Contracting Standards for Dual Eligible Special Needs Plan (D–SNP) Look-Alikes (§ 422.514)

Special needs plans (SNPs) are MA plans created by the MMA that are specifically designed to provide targeted care and limit enrollment to special needs individuals. Under section 1859 of the Act, SNPs are able to restrict enrollment to: (1) Institutionalized individuals, who are currently defined in § 422.2 as those residing or expecting to reside for 90 days or longer in a long term care facility; (2) individuals entitled to medical assistance under a State Plan under Title XIX; or (3) other individuals with certain severe or disabling chronic conditions who would benefit from enrollment in a SNP. As of July 2019, there are 321 SNP contracts with 734 SNP plans that have at least 11 members, including all of the following:

- 480 dual eligible SNPs (D–SNPs).
- 125 institutional SNPs (I–SNPs).
- 129 chronic or disabling condition SNPs (C–SNPs).[9]

Beneficiaries who are dually eligible for both Medicare and Medicaid can face significant challenges in navigating the two programs, which include separate or overlapping benefits and administrative processes. Fragmentation between the two programs can result in a lack of coordination for care delivery, potentially resulting in—(1) missed opportunities to provide appropriate, high-quality care and improve health outcomes; and (2) undesirable outcomes, such as avoidable hospitalizations and poor beneficiary experiences. Advancing policies and programs that integrate care for dually eligible individuals is one way in which we seek to address such fragmentation. Under plans that offer integrated care, dually eligible individuals receive the full array of Medicaid and Medicare benefits through a single delivery system, thereby improving care coordination, quality of care, and beneficiary satisfaction, and reducing administrative burden. Some studies have shown that highly integrated managed care programs perform well on quality of care indicators and enrollee satisfaction.[10]

D–SNPs are intended to integrate or coordinate care for this population more effectively than standard MA plans or the original Medicare fee-for-service program by focusing enrollment and care management on dually eligible individuals. As of July 2019, approximately 2.6 million dually eligible individuals (1 of every 5 dually eligible individuals) were enrolled in 480 D–SNPs.

Federal statute and implementing regulations have established several requirements for D–SNPs in addition to those that apply to all MA plans, including all of the following:

- *Health risk assessment.* Section 164 of MIPPA amended section 1859(f) of the Act to require all SNPs to conduct an initial assessment and an annual reassessment of an enrollee's physical, psychosocial, and functional needs. Implementing regulations are codified at § 422.101(f)(1)(i).
- *Model of care.* Section 164 of MIPPA amended section 1859(f) of the Act to require all SNPs to have in place an evidence-based model of care with appropriate networks of providers and specialists. Implementing regulations are codified at § 422.101(f).
- *Comprehensive written statement.* Section 164 of MIPPA amended section 1859(f) of the Act to require D–SNPs to provide each prospective enrollee, prior to enrollment, with a comprehensive written statement that describes the benefits and cost-sharing protections to which the beneficiary is entitled under Medicaid and which of those Medicaid benefits are covered by the D–SNP. Implementing regulations are codified at § 422.111(b)(2)(iii).
- *State Medicaid agency contract.* Section 164 of MIPPA also amended section 1859(f) of the Act to require that D–SNPs contract with the state Medicaid agency to provide benefits, or arrange for the provision of Medicaid benefits, which may include long-term care services consistent with state policy, to which an individual is entitled. Notwithstanding this requirement for D–SNPs, section 164(c)(4) of MIPPA stipulated that a state is in no way obligated to contract with a D–SNP, which therefore provides states with significant control over the availability of D–SNPs. Implementing regulations are codified at § 422.107.

These requirements promote coordination of care. Additionally, the state Medicaid agency contracting requirement allows states the flexibility to require greater integration of Medicare and Medicaid benefits from the D–SNPs in their markets. For example, to develop products that integrate Medicare and Medicaid coverage, several states—including Arizona, Hawaii, Idaho, Massachusetts, Minnesota, New Jersey, and Tennessee—operate Medicaid managed care programs for dually eligible individuals in which the state requires that the Medicaid managed care organizations (MCOs) serving dually eligible individuals offer a companion D–SNP product. These states also require specific care coordination or data sharing activities in their contracts with D–SNPs.[11]

[9] Centers for Medicare & Medicaid Services. *SNP Comprehensive Report.* (July 2019) Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

[10] See Kim, H., Charlesworth, C.J., McConnell, K.J., Valentine, J.B., and Grabowski, D.C. ''Comparing Care for Dual-Eligibles Across Coverage Models: Empirical Evidence From Oregon'', *Medical Care Research and Review,* (November 15, 2017) 1–17. Retrieved from *http://journals.sagepub.com/doi/abs/10.1177/1077558717740206;* Anderson, W.L., Feng, Z., & Long, S.K. *Minnesota Managed Care Longitudinal Data Analysis,* prepared for the U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE) (March 31, 2016). Retrieved from *https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis;* Health Management Associates. *Value Assessment of the Senior Care Options (SCO) Program* (July 21, 2015). Retrieved from *http://www.mahp.com/wp-content/uploads/2017/04/SCO-White-Paper-HMA-2015_07_20-Final.pdf;* and Medicare Payment Advisory Committee. ''Chapter 2, Care coordination programs for dual-eligible beneficiaries.'' In *June 2012 Report to Congress: Medicare and Health Care Delivery System* (June 16, 2012). Retrieved from *http://www.medpac.gov/docs/default-source/reports/jun12_entirereport.pdf?sfvrsn=0.*

[11] See Verdier, J., Kruse, A., Sweetland Lester, R., Philip, A.M., and Chelminsky, D. *State Contracting*

More recently, section 50311(b) of the BBA of 2018 amended section 1859 of the Act to add new requirements for D–SNPs, beginning in 2021. These requirements, along with clarifications to existing regulations, were codified in the April 2019 final rule (84 FR 15680 through 15844).

• *Minimum integration standards.* As required under section 1859(f)(8)(D)(i) of the Act, as added by the BBA of 2018, all D–SNPs must meet certain new minimum criteria for integration of Medicare and Medicaid benefits for 2021 and subsequent years. To achieve the minimum integration standards, we codified in the April 2019 final rule that a D–SNP must: (1) Be a fully integrated dual eligible (FIDE) SNP; (2) be a highly integrated dual eligible (HIDE) SNP; or (3) have a contract with the state to notify the state, or the state's designee, of high-risk individuals' hospital and skilled nursing facility admissions. Section 1859(f)(8)(D)(ii) of the Act provides that for the years 2021 through 2025, if the Secretary determines that a D–SNP fails to meet one of these integration standards, the Secretary may prevent the D–SNP from enrolling new members. These provisions are codified in amendments to §§ 422.2, 422.107(d), and 422.752(d) that are effective January 1, 2021.

• *Medicaid coordination:* We interpreted the meaning of the requirement in section 1859(f)(3)(D) of the Act, originally codified at § 422.107(b), that the MA organization has responsibility under the contract for providing benefits or arranging for benefits to be provided for individuals entitled to Medicaid as requiring a D–SNP, at a minimum, to coordinate the delivery of Medicare and Medicaid benefits. This requirement is reflected in an amendment to the D–SNP definition at § 422.2, effective January 1, 2020. In addition, an amendment to § 422.562(a)(5), also effective January 1, 2020, requires all D–SNPs to make assistance available to individuals filing a grievance or appeal for Medicaid services.

• *Unified appeals and grievances.* Sections 1859(f)(8)(B) and (C) of the Act require development of unified grievance and appeals processes for D–SNPs, to the extent feasible, to be applicable beginning 2021. We finalized definitions at § 422.561 and implementing regulations, effective January 1, 2021, at §§ 422.560, 422.562, 422.566, 422.629 through 422.634, 438.210, 438.400, and 438.402 in the April 2019 final rule. For 2021 and subsequent years, integrated D–SNPs with exclusively aligned enrollment, termed ''applicable integrated plans,'' must establish integrated grievance and appeals systems using integrated timeframes, notices, and processes. New rules under § 422.632, also effective January 1, 2021, require continuation of benefits pending appeal for enrollees in applicable integrated plans.

The pattern of federal legislation, CMS rulemaking, and state use of D–SNP contracting requirements has incrementally created new requirements for D–SNPs that have generally promoted additional beneficiary protections, coordination of care, and integration of Medicare and Medicaid coverage for dually eligible individuals. While many of these requirements impose additional burdens for D–SNPs, they have not impeded enrollment growth in these plans. Total D–SNP enrollment has more than doubled from one million in 2010 to 2.6 million in 2019.[12] Participation of MA organizations is robust, and most markets are stable and competitive.

In its June 2018 and 2019 reports to Congress, the Medicare Payment Advisory Commission (MedPAC) describes the emergence of ''D–SNP look-alike'' plans that have similar levels of dual eligible enrollment as D–SNPs. For example, MedPAC analysis of 2016 data in select California counties found that, as a percentage of total enrollment, dually eligible individuals accounted for 97 percent of enrollment in D–SNPs and 95 percent in D–SNP look-alikes—compared to 10 percent in other MA plans. Analysis of 2017 enrollment nationally showed multiple D–SNP look-alikes in which dually eligible individuals account for more than 95 percent of total enrollment.[13] Although section 1859(b)(6) of the Act establishes D–SNPs as the only type of MA plan that can exclusively enroll dually eligible individuals, the data show that D–SNP look-alikes have levels of dual eligible enrollment that are virtually indistinguishable from those of D–SNPs and far above those of the typical MA plan.

We believe the low enrollment of non-dually eligible individuals in D–SNP look-alikes results from benefits and cost-sharing that, like the benefits and cost-sharing offered by D–SNPs, are designed to attract only dually eligible individuals. In contrast to non-SNP MA plans, both D–SNPs and D–SNP look-alikes allocate a lower percentage of MA rebate dollars received under the bidding process at § 422.266 to reducing Medicare cost-sharing and a higher percentage of rebate dollars to supplemental medical benefits such as dental, hearing, and vision services. With such a benefit design, many D–SNP look-alikes technically require members to pay higher cost sharing on Parts A and B services than most MA plans require, which we believe dissuades most non-dually eligible Medicare beneficiaries from enrolling. However, because most dually eligible individuals are Qualified Medicare Beneficiaries (QMBs) who are not required to pay Medicare cost sharing, we believe they are not dissuaded from enrolling in these non-D–SNPs by the relatively higher cost sharing. A similar dynamic exists for Part D premiums and high deductibles, both of which are covered by the Part D low-income subsidy that dually eligible individuals receive. We believe that such benefit designs are unattractive for Medicare beneficiaries who are not dually eligible individuals because they would need to cover these costs out-of-pocket. Despite the similarities with D–SNPs in terms of levels of dual eligible enrollment and benefits and cost-sharing design, D–SNP look-alikes are regulated as non-SNP MA plans and are not subject to the federal regulatory and state contracting requirements applicable to D–SNPs.

D–SNP look-alikes first emerged in certain California markets in 2013, after the state placed enrollment restrictions on D–SNPs in areas served by Medicare-Medicaid Plans (MMPs) participating in the Financial Alignment Initiative. Enrollment in D–SNP look-alikes has increased substantially since that time. In these California markets, MedPAC found that D–SNP look-alike enrollment grew from around 5,000 in 2013 to over 95,000 in 2017.[14] MedPAC also explored enrollment trends more broadly, identifying 31 non-SNP

with Medicare Advantage Dual Eligible Special Needs Plans: Issues and Options (November 2016). Retrieved from *https://www.integratedcareresourcecenter.com/sites/default/files/ICRC_DSNP_Issues_Options.pdf.*

[12] Centers for Medicare & Medicaid Services. *SNP Comprehensive Report* (July 2010 & July 2019). Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

[13] See *June 2018 MedPAC Report to Congress, Chapter 9* at *http://medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0* and *June 2019 MedPAC Report to Congress, Chapter 12* at *http://www.medpac.gov/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf?sfvrsn=0.*

[14] See *June 2018 MedPAC Report to Congress, Chapter 9* at *http://medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0.*

plans[15] operating in 2017 in which dually eligible individuals comprised 80 percent or more of total plan enrollment. These 31 plans, which operated in 10 states (mostly in California and Florida), included approximately 151,000 enrollees. MedPAC estimated that in 2019 enrollment would increase to 193,000 beneficiaries in 54 D–SNP look-alikes across 13 states.[16]

It is not clear that D–SNP look-alikes are essential to the implementation of the Medicare Advantage program or to access to coverage or care for Medicare beneficiaries. Unlike the non-SNP MA plans in which many dually eligible individuals enroll, D–SNP look-alikes do, however, have the near-exclusive levels of dual eligible enrollment that the statute envisions only for D–SNPs that must meet additional Medicare and Medicaid coordination and integration requirements. Most D–SNP look-like enrollment is in markets that feature numerous other plan choices for beneficiaries. Only about 1.2 percent of dually eligible enrollees in traditional MA plans (that is, non-SNP MA plans) are in plans with 80 percent or higher dually eligible enrollment. The data also show that traditional MA plans that are not D–SNP look-alikes can attract dually eligible enrollment; 97 percent of dually eligible individuals enrolled in non-SNP MA plans are in a plan with dual eligible enrollment of 30 percent or less.[17]

The proliferation and growth of D–SNP look-alikes raises multiple areas of concern as follows:

• *Effective implementation of BBA of 2018 requirements.* As discussed earlier in this proposed rule, beginning in contract year 2021, all D–SNPs must meet new minimum criteria for Medicare and Medicaid integration. D–SNP look-alikes hinder meaningful implementation of these statutory requirements. By creating and offering these D–SNP look-alikes that target the same dually eligible individuals who are intended to benefit from integrated D–SNPs, MA organizations are circumventing the new integration requirements.

• *Meaningful integration.* Several states use the state Medicaid agency contracting requirements for D–SNPs at § 422.107 to promote greater Medicare-Medicaid integration. In such states, the state and D–SNP establish specific care coordination protocols, data sharing processes, and other activities to promote better beneficiary experiences. Proliferation of D–SNP look-alikes, for which the same state contracting requirement does not apply, impedes states from using their contracting authority under section 1859 of the Act to ensure that plans predominantly serving dually eligible individuals are working toward those goals. In its comments to CMS for the April 2019 final rule, the Medicaid and CHIP Payment and Access Commission (MACPAC) expressed concern that the growth of D–SNP look-alikes may undermine efforts to promote increased integration through D–SNPs and urged CMS to continue to monitor the growth of look-alikes and determine if further action is needed.[18] As we noted earlier, studies have shown that highly integrated managed care programs perform well on quality of care indicators and enrollee satisfaction.

• *Care coordination requirements.* To better serve the dually eligible population, MIPPA and implementing regulations require D–SNPs to provide periodic health risk assessments, develop individualized care plans for their members, and develop and seek CMS approval for their models of care. These requirements do not apply to D–SNP look-alikes. As a result, nothing requires the D–SNP look-alikes to deliver the types of care coordination that Congress established as statutory requirements for plans that are designed for dually eligible individuals.

• *Beneficiary confusion.* The prevalence of the D–SNP look-alikes has led to instances of misleading marketing by brokers and agents that misrepresent to dually eligible individuals the characteristics of such look-alike plans, especially where the plans have marketed themselves as being special Medicaid-focused plans. We continue to learn of these marketing practices from our own review of broker materials, investigating complaints we have received, and reports from advocacy organizations.[19] Confusing and misleading marketing efforts may violate § 422.2268(a)(1) and (2) which this proposed rule proposes to redesignate as § 422.2262(a)(1)(i) and (iii) which prohibits MA organizations from providing information that is inaccurate or misleading and from engaging in activities that could mislead or confuse Medicare beneficiaries or misrepresent the MA organization. For that reason, and as discussed elsewhere in this proposed rule, we propose at § 422.2262(a)(1)(xvi) to codify previous subregulatory guidance from the Medicare Communications and Marketing Guidelines prohibiting MA organizations, with respect to their non-D–SNP plans, from marketing their plan as if it were a D–SNP, implying that their plan is designed for dually eligible individuals, targeting their marketing efforts exclusively to dually eligible individuals, or claiming a relationship with the state Medicaid agency, unless a contract to coordinate Medicaid services for that plan is in place.

We sought comments on the impact of D–SNP look-alikes in Medicare and Medicaid in the 2020 Draft Call Letter.[20] Specifically, we sought comment on topics related to the extent to which D–SNP look-alikes impact informed consumer choice; competition and innovation; the provision of high-quality coordinated care that addresses the full spectrum of dually eligible individuals' care and service needs; state Medicaid policy and operations; financial incentives; provider burden; and development and sustainability of products for dually eligible individuals through which an enrollee can receive all Medicare and Medicaid services from one organization.

As discussed in the 2020 Final Call Letter, we received comments from a range of stakeholders, including states, beneficiary advocates, and MA organizations and Medicaid MCOs.[21] Overall, the comments reinforced our concern that the proliferation of D–SNP look-alikes impedes progress toward developing products that meaningfully integrate Medicare and Medicaid benefits for dually eligible individuals. Commenters believed that D–SNP look-alikes allow MA organizations to circumvent enrollment restrictions and federal regulatory and state contracting requirements for D–SNPs and MMPs, undercutting efforts to lower costs and improve the quality of care.

As we noted in the 2020 Final Call Letter, commenters highlighted three areas that warranted further investigation and analysis and potential rulemaking: Benefit design and

[15] MedPAC also excluded employer group waiver plans (EGWPs) and a select group of medical savings account (MSA) plans.

[16] See *June 2018 MedPAC Report to Congress, Chapter 9* at *http://medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0* and *June 2019 MedPAC Report to Congress, Chapter 12* at *http://www.medpac.gov/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf?sfvrsn=0.*

[17] Ibid.

[18] Available at *https://www.macpac.gov/wp-content/uploads/2018/12/Comments-on-Changes-to-MA-the-Medicare-prescription-drug-benefit-PACE-Medicaid-fee-for-service-and-managed-care.pdf.*

[19] Justice in Aging, *Dual Eligible Special Needs Plan (D–SNP) Look-Alikes: A Primer* (July 2019) at *https://www.justiceinaging.org/wp-content/uploads/2019/07/D-SNP-Look-Alikes-A-Primer.pdf.*

[20] Available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.*

[21] Ibid.

nondiscrimination; beneficiary education, marketing, and broker compensation; and enhanced requirements for MA plans with high proportions of dually eligible enrollees. Some stakeholders suggested that benefit design used by D–SNP look-alikes appears to violate the prohibition at § 422.100(f)(2) against benefit designs that are discriminatory and against steering subsets of beneficiaries to specific plans, since their design targets dually eligible individuals.

We also received broad support for efforts to ensure that MA organizations do not market D–SNP look-alikes as plans that coordinate Medicaid benefits, as particularly suited to dually eligible individuals, or as uniquely subject to rules that protect dually eligible individuals from cost sharing or for which Medicaid pays the full amount of plan cost sharing. Lastly, several commenters recommended that CMS require MA plans with high proportions of dually eligible individuals to meet D–SNP regulatory requirements, including the requirement to contract with the state Medicaid agency.

To address these concerns, we are proposing at § 422.514(d) that CMS not enter into or renew a contract for a D–SNP look-alike in any state where there is a D–SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals. We also propose to establish procedures for transitioning enrollees from D–SNP look-likes to other MA plans in new regulation text at § 422.514(e). The proposed new contracting standards would effectively ensure all MA plans that predominantly serve dually eligible individuals integrate delivery of Medicare and Medicaid services and coordinate care consistent with the statutory and regulatory requirements for D–SNPs wherever it is feasible to do so.

Under our authority to adopt standards implementing the Part C statute and to add contract terms in sections 1856(b) and 1857(e)(1) of the Act, we are proposing to establish contracting standards for MA organizations based on their projected dually eligible enrollment in plan bids or on the proportion of dually eligible enrollees actually enrolled in the plan. A high rate of enrollment by dually eligible individuals in a non-D–SNP would allow us to identify non-SNP MA plans that are intended to predominantly enroll dually eligible individuals (that is, D–SNP look-alikes). We propose exceptions to these contracting standards for all SNPs. We believe that our proposal is an effective way to ensure that MA organizations do not undermine the statutory requirements established for D–SNPs by designing non-SNP MA plans to predominantly enroll dually eligible individuals. We believe that failure to adopt these exceptions could compromise the statutory and regulatory framework for D–SNPs. Any MA organization, by designing its benefits and outreach strategy to target dually eligible enrollment, practices that the enrollment patterns of D–SNP look-alikes show MA organizations are readily adopting, can offer an MA plan with high rates—in some cases almost 100 percent—of dually eligible enrollment without implementing any of the care management or Medicaid coordination activities that federal law requires of D–SNPs. States' ability to set contract terms for D–SNPs, including terms that limit contracted D–SNPs to entities that deliver integrated Medicare and Medicaid benefits, as provided under section 1859 of the Act, is likewise subverted by D–SNP look-alikes. Our proposal is especially critical as we approach implementation of new D–SNP requirements included in the BBA of 2018.

To prevent the undermining of the statutory and regulatory framework for D–SNPs, we therefore propose to establish a new regulation precluding CMS from entering into or renewing a contract for an MA plan that an MA organization offers, or proposes to offer, with enrollment of dually eligible individuals that exceeds specific enrollment thresholds. This proposed regulation would apply in any state where there is a D–SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals. Section 1856(b)(1) of the Act provides the Secretary with the authority to establish in regulation other standards not otherwise specified in statute that are both consistent with Part C statutory requirements and necessary to carry out the MA program. Our proposed regulations would ensure applicability and compliance with the statutory framework for D–SNPs. Additionally, section 1857(e)(1) of the Act authorizes the Secretary to establish MA organization contract terms and conditions that are necessary and appropriate and not inconsistent with other Part C statutory requirements. We believe that our proposed contract terms prohibiting the offering of D–SNP look-alikes is not inconsistent with the Part C statute and is necessary and appropriate to retain the integrity of the D–SNP statutory framework. Under the statute, only D–SNPs can primarily enroll dually eligible individuals, and D–SNPs must meet certain requirements. Our proposal would ensure that a non-SNP MA plan that, in practice, enrolls primarily dually eligible individuals under the conditions outlined in our proposal does not skirt the specific statutory and regulatory requirements designed to meet the specific needs of dually eligible individuals.

We propose not to enter into or renew MA contracts for an MA plan for an upcoming plan year when that MA plan is identified as exceeding specific enrollment thresholds for dually eligible individuals. However, MA organizations with plans identified as exceeding the enrollment threshold that also have approved D–SNPs for the following plan year would be permitted to transition dually eligible enrollees from D–SNP look-alikes to D–SNPs for which the individuals are eligible. We would permit this transition process to minimize disruptions to beneficiary coverage and allow enrollees in these D–SNP look-alikes to benefit from the statutory and regulatory care coordination and Medicaid integration requirements. We describe the specific changes we are proposing to § 422.514 as follows.

We propose changing the title of § 422.514 by removing the word ''minimum'' because the changes we propose to § 422.514 reflect an additional type of enrollment requirement beyond the minimum enrollment requirements currently articulated in § 422.514. We also propose to change the title of paragraph (a) from ''Basic rule'' to ''Minimum enrollment rules'' for clarity due to the proposed change to the scope of § 422.514.

We propose a new paragraph (d) to establish new contract requirements related to dual eligible enrollment. The proposed requirement at paragraph (d) would apply for an MA plan that is not a special needs plan for special needs individuals as defined in § 422.2. We propose applying this requirement only to non-SNP plans to allow for the predominant dually eligible enrollment that characterizes D–SNPs, I–SNPs, and some C–SNPs by virtue of the populations that the statute expressly permits each type of SNP to exclusively enroll. For D–SNPs, the rationale for the exception is obvious—these MA plans enroll dually eligible individuals by statute. I–SNPs, by virtue of enrolling institutionalized individuals, or community-residing individuals who, but for the long-term services and supports they receive, otherwise reside in a long-term care institution, typically have high proportions of dually eligible individuals who qualify to receive

Medicaid long-term care benefits. In July 2017, 92 percent of I–SNP enrollees were dually eligible individuals.[22] Certain C–SNPs also have a relatively high proportion of dually eligible individuals because the chronic conditions these plans target are more prevalent among dually eligible individuals. For example, in July 2017, dually eligible individual enrollment in one end-stage renal disease (ESRD) C–SNP was 49 percent of total enrollment, in one HIV/AIDS C–SNP was 68 percent of total enrollment, and in one chronic and disabling mental health conditions C–SNP was 83 percent of total enrollment.[23] We would not want our proposed requirements to limit C–SNP enrollment by dually eligible individuals who could benefit from a plan that employs a specialized model of care, periodic health risk assessments, and other techniques that result in specialized, comprehensive care for individuals with certain chronic conditions.

The proposed requirement at paragraph (d) would be limited to states where there is a D–SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals, such as MMPs. We propose this limitation because it is only in such states that the implementation of D–SNP requirements necessitates our proposed new contracting requirements. That is, in a state with no D–SNPs or comparable managed care plans like MMPs, the D–SNP requirements have not had any relevance historically. There are no plans contracted with the state to implement the D–SNP requirements or otherwise integrate Medicare and Medicaid services, and therefore the operation of a D–SNP look-alike would not have any material impact on the full implementation of federal D–SNP requirements. In such states, the existence of D–SNP look-alikes is not impeding state or federal implementation of any requirements for enhanced care coordination and Medicaid integration by providing a vehicle for MA organizations to avoid compliance with those requirements that are imposed on D–SNPs or comparable managed care plans like MMPs. Therefore, we do not believe it is critical for our proposed requirements in paragraph (d) to apply in such states.

As of July 2019, eight states do not have any D–SNPs. We believe there are two main reasons for the absence of D–SNPs in these states. First, the rural nature of some states makes it challenging for any MA plan, including a D–SNP, to operate because of the sparse Medicare population and the difficulty in establishing networks. Second, some state Medicaid agencies have decided not to contract with any D–SNPs, either because the agency is not pursuing integration of Medicare and Medicaid through managed care, or is pursuing integrated care through MMPs.

We believe the proposed limitation on the states where the proposed dual eligible enrollment requirement would apply would continue to protect states' ability to contract with plans—including for Medicaid behavioral health services and long-term supports and services—in a manner that promotes integration and coordination of benefits and a more seamless experience for dually eligible individuals in such plans. Based on the type of plan, states use different contracting mechanisms to establish such requirements. In particular, states establish three-way contracts with MMPs, state Medicaid agency contracts with D–SNPs, and other contracts with Medicaid MCOs affiliated with D–SNPs for the delivery of Medicaid benefits. Each type of contract between the state and plan can effectively establish integration and coordination of benefits requirements.

However, we recognize that the limitation would allow, in certain states, D–SNP look-alikes that do not meet the minimum D–SNP requirements for data sharing or care coordination. We seek comment on whether the absence of these data sharing and care coordination requirements for D–SNP look-alikes in states where they could continue to operate under our proposed rule disadvantages the dually eligible individuals in D–SNP look-alikes and whether we should extend the proposed requirement at paragraph (d) to all states.

We propose to add new paragraphs (d)(1) and (2) that would require that CMS not enter into or renew a contract, for plan year 2022 or subsequent years, for an MA plan that is a non-SNP plan that either:

- Projects in its bid submitted under § 422.254 that 80 percent or more of the plan's total enrollment are enrollees entitled to medical assistance under a state plan under Title XIX, or
- Has actual enrollment, as determined by CMS using the January enrollment of the current year, consisting of 80 percent or more of enrollees who are entitled to medical assistance under a state plan under Title XIX, unless the MA plan has been active for less than one year and has enrollment of 200 or fewer individuals at the time of such determination.

We believe that using either enrollment scenario is necessary to ensure that both new D–SNP look-alikes are not offered and that current, or existing, D–SNP look-alikes are not continued.

Proposed paragraph (d)(2), which would allow us to identify D–SNP look-alikes based on actual enrollment, would limit the prohibition to MA plans that have been active for one or more years and with enrollment equal to or greater than 200 individuals at the time of CMS' determination under proposed paragraph (d)(2). This limitation on our proposed contract requirement during a plan's first year is important because an early enrollment pattern may not be representative of the enrollment profile the plan will experience at a point of greater maturity.

To provide an example of how CMS would implement proposed paragraph (d)(2) in the first year, CMS would review MA plan enrollment data for January 2021 to determine if actual enrollment consists of 80 percent or more of enrollees who are entitled to medical assistance under a state plan under Title XIX. CMS would not enter into or renew the contract for contract year 2022 for an MA plan that exceeds the 80 percent threshold unless the MA plan has been active for less than one year and has January 2021 enrollment of 200 or fewer individuals.

We believe focusing on the proportion of dually eligible enrollment, both in bids and actual enrollment, is the best way to identify D–SNP look-alikes because it is the net result of benefit design and marketing strategies and less subject to gaming by plans than other alternatives, as discussed later in this preamble. We propose a threshold for dually eligible enrollment at 80 percent of a non-SNP MA plan's enrollment because it far exceeds the share of dually eligible individuals in any given market and, therefore, would not be the result for any plan that had not intended to achieve high dually eligible enrollment. MedPAC analysis shows that in most MA markets, the proportion of dually eligible individuals as a percentage of total enrollment is clustered in the 10 to 25 percent range and in no county exceeds 50 percent.[24] We believe the proportion of dually eligible enrollment as a percentage of

[22] CMS, Chronic Conditions Data Warehouse, Part D Plan Characteristics File and Master Beneficiary Summary File, Final 2017 MBSF created in January 2019.

[23] Ibid.

[24] *June 2019 MedPAC Report to Congress, Chapter 12* at *http://www.medpac.gov/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf?sfvrsn=0.*

total plan enrollment is therefore a reliable indicator or proxy for identifying a non-SNP MA plan that the MA organization intends to have exclusive or predominantly dually eligible enrollment in without being subject to the D–SNP integration and care coordination requirements. MedPAC data show that our proposed threshold would have minimal impact on total dually eligible enrollment in non-SNP MA plans. Among dually eligible enrollees in traditional MA plans, only about 1.2 percent are in plans in which dually eligible individuals make up 80 percent or more of total plan enrollment. Also, 97 percent of dually eligible individuals enrolled in traditional MA plans are enrolled in a plan with 30 percent or less dually eligible enrollment, which indicates that traditional MA plans do not have to create D–SNP look-alikes to attract dually eligible individuals.[25]

We considered an alternative discussed by MedPAC in its June 2019 report to Congress for identifying traditional MA plans with predominantly dually eligible enrollment: Setting the bar at the higher of 50 percent dually eligible enrollment or the proportion of dually eligible MA-eligible individuals in the plan service area plus 15 percentage points. We also considered setting a lower threshold for dually eligible enrollment at a point between 50 percent and our proposed 80 percent threshold. However, we opted to propose an enrollment threshold of 80 percent or higher as an indicator that the plan is designed to attract disproportionate dually eligible enrollment because it aligns with MedPAC's 2019 research findings, provides a threshold that would be easier for MA organizations to determine prospectively, and would be easier for CMS to implement. We seek comment on whether these alternative enrollment thresholds are preferable.

Under our proposal for paragraph (d)(2), we would annually make the determination whether an MA organization has a non-SNP MA plan with actual enrollment exceeding the established threshold using the plan's enrollment in January of the current year. We intend to make such evaluations and issue the necessary information to affected MA organizations early in the coverage year. Even without a notice from CMS, we expect that each MA organization would be able to independently determine the level of dually eligible enrollment in its MA plan. Upon receiving the notice from CMS that this proposed prohibition on contracting with D–SNP look-alikes is triggered, the MA organization would then have the opportunity to make an informed business decision to: (1) As necessary, apply and contract for a new D–SNP for the forthcoming contract year; (2) create a new MA plan or plans through the annual bid submission process; or (3) terminate the D–SNP look-alike plan and not submit a bid for the following contract year.

In proposed paragraph (e), we propose a process and procedures for transitioning individuals who are enrolled in a D–SNP look-alike to another MA–PD plan (or plans) offered by the MA organization to minimize disruption as a result of the prohibition on contract renewal for existing D–SNP look-alikes. Enrollees in MA plans that an MA organization cannot continue to operate as a result of our proposal may choose new forms of coverage for the following plan year, including a new MA or MA–PD plan or through the original Medicare fee-for-service program. Under our proposal, an MA organization with a non-SNP MA plan determined to meet the enrollment threshold in proposed paragraph (d)(2) could transition enrollees into another MA–PD plan (or plans) offered by the same MA organization, as long as any such MA–PD plan meets certain proposed criteria described in this section. As stated in paragraph (e)(2), this proposed transition process would allow MA enrollees to be transitioned from one MA plan offered by an MA organization to another MA–PD plan (or plans) without having to fill out an election form or otherwise indicate their enrollment choice as typically required, but it would also permit the enrollee to make an affirmative choice for another MA plan of his or her choosing. Enrollees would still have the opportunity to choose their own plan during this transition process because of how the proposed transition process would overlap with the annual coordinated election period.

Proposed paragraph (e)(1) specifies that, for coverage effective January 1 of the next year, the MA organization could only transition individuals from the D–SNP look-alike that is not being renewed into one or more MA plans (including a D–SNP) if such individuals are eligible to enroll in the receiving plan(s) in accordance with §§ 422.50 through 422.53. Thus, the individual would have to reside in the service area of the new plan and otherwise meet eligibility requirements for it. The proposed process would allow, but not require, the MA organization to transition dually eligible enrollees from a D–SNP look-alike into one or more D–SNPs offered under the MA organization, or another MA organization that shares the same parent organization as the MA organization, and therefore allow enrollees to benefit not only from continued coverage under the same parent organization but also from the care coordination and Medicaid benefit integration offered by a D–SNP.

We also propose at paragraphs (e)(1)(i) through (iii) specific criteria for any MA plan to receive enrollment through this transition process. Our policy goal for this process is to ensure that enrollees receive coverage under their new MA plan that is similarly affordable as the plan that would not be permitted for the next year. Under paragraph (e)(1)(i), we propose to allow a terminating D–SNP look-alike to transition enrollment to another non-SNP plan (or plans) only if the resulting total enrollment in each of the MA plans receiving enrollment consists of less than 80 percent dually eligible individuals. SNPs receiving transitioned enrollment would not be subject to the proposed dual eligible enrollment requirement. The percent of dually eligible individuals in the resulting total enrollment would have to be determined prospectively in order for us to make a timely decision on whether to allow for an MA organization to transition enrollment into a non-SNP MA plan or plans. As described at proposed paragraph (e)(3), we would make such determination by adding the cohort of enrollees that the MA organization proposes to enroll into a different non-SNP plan to the April enrollment of the receiving plan and calculating the resulting percent of dually eligible enrollment. We would make this calculation for each non-SNP plan into which the MA organization proposes to transition enrollment. This proposed criterion would ensure that the enrollment transitions under this regulation do not result in another non-SNP MA plan being treated as a D–SNP look-alike under proposed paragraph (d). Proposed paragraph (e)(1)(ii) would require that any plan receiving transitioned enrollment be an MA–PD plan as defined in § 422.2. Proposed paragraph (e)(1)(iii) would require that any MA plan receiving transitioned enrollment from a D–SNP look-alike have a combined Part C and D beneficiary premium of $0 after application of the premium subsidy for

[25] See *June 2018 MedPAC Report to Congress, Chapter 9* at *http://medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0* and *June 2019 MedPAC Report to Congress, Chapter 12* at *http://www.medpac.gov/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf?sfvrsn=0.*

full subsidy eligible individuals described at § 423.780(a).

As proposed in paragraph (e)(2)(ii), the MA organization would be required to describe changes to MA–PD benefits and provide information about the MA–PD plan into which the individual is enrolled in the Annual Notice of Change that the MA organization must send, consistent with § 422.111(a), (d), and (e) and proposed § 422.2267(e)(3). Consistent with § 422.111(d)(2), enrollees would receive this Annual Notice of Change (ANOC) describing the change in plan enrollment and any differences in plan enrollment at least 15 days prior to the first day of the annual election period. By proposing that this information is provided before the annual election period through this reference to the ANOC, we believe that we are ensuring that each enrollee affected by a transition under this proposal would have the information necessary to decide if they wish to change plans rather than be transitioned to the MA organization's other plan. By timing the notice with the annual open enrollment period, our proposal ensures that affected enrollees retain the opportunity to choose another MA plan or the original Medicare fee-for-service program and a Prescription Drug Plan.

As proposed in paragraph (e)(4), in cases where an MA organization does not transition some or all current enrollees from a D–SNP look-alike plan to one or more of the MA organization's other plans as provided in proposed paragraph (e)(1), it would be required to send affected enrollees a written notice consistent with the non-renewal notice requirements at § 422.506(a)(2). This proposal ensures that affected enrollees who would otherwise be disenrolled to the original Medicare fee-for-service program have an opportunity during the annual open enrollment period to make a different enrollment election.

This proposed transition process is conceptually similar to ''crosswalk exception'' procedures historically allowed by CMS and proposed at § 422.530, as described in section VI.C. of this proposed rule. However, in contrast to the proposed crosswalk exceptions, our proposal would allow the transition process to apply across legal entities offered by MA organizations under the same parent organization, as well as different plan types (for example, non-SNP to SNP). Allowing this type of enrollment transition process would minimize disruptions in coverage for dually eligible individuals enrolled in a D–SNP look-alike (who could be transitioned to a D–SNP or a non-D–SNP) and the small number of Medicare-only individuals enrolled in a D–SNP look-alike plan (who could be transitioned into a non-SNP MA plan operated by the same MA organization). Because this transition process is not the same as the crosswalk process, our proposal codifies it as part of § 422.514.

We considered an alternative that would require transitioning any dually eligible individuals into a D–SNP for which they were eligible if such a plan is offered by the MA organization. We opted for proposing a less prescriptive set of transition rules, recognizing a potentially wide array of transition scenarios, but seek comment on this alternative. In addition, we seek comment on whether additional criteria for the receiving plan are necessary to protect beneficiaries who are affected by this proposed prohibition on renewing MA plans that meet the criteria in proposed § 422.514(d).

We intend for the transition process to take effect in time for D–SNP look-alikes operating in 2020 to utilize the transition process for enrollments to be effective January 1, 2021. This will allow current MA–PD plans that expect to meet the enrollment threshold in proposed paragraph (d)(2) to retain some or all of their current enrollment by transitioning these individuals to other MA–PD plans offered by the same MA organization a year before CMS implements any plan terminations under this proposal. Contract terminations for plans that are specified in proposed paragraph (d)(2) would take effect no earlier than December 31, 2021, because, as specified in the proposed regulation text, such terminations would apply only beginning for plan year 2022. However, the proposed provision at paragraph (e)(1) allowing an MA organization to transition enrollees from a D–SNP look-alike plan into one or more MA–PD plans offered by that MA organization would be effective after the publication of a final rule in 2020. That is, if our proposal is finalized, we would work with plans that expect to have enrollment of dually eligible individuals that exceeds the enrollment threshold in proposed paragraph (d)(2) for Contract Year 2021 to confirm eligibility for the transition process and take necessary operational steps in 2020 to allow transition of enrollees from those plans into new MA–PD plans offered by the same MA organization on January 1, 2021, because CMS would not renew those contracts for 2022.

Overall, our proposal focuses on dually eligible beneficiaries as a percentage of a plan's total enrollment. We considered using alternative criteria instead of, or in addition to, the percentage of projected or actual dually eligible enrollment, to identify non-SNP MA plans designed to exclusively or predominantly enroll dually eligible individuals. In particular, we considered identifying D–SNP look-alikes by the benefit design these plans typically offer—relatively high Parts A and B cost sharing and a high Part D deductible that make the plans unattractive to Medicare-only beneficiaries, supplemental benefits like dental and hearing services and over-the-counter drugs that mimic typical D–SNP offerings, and a premium for Part D coverage that is fully covered by the Part D low-income subsidy. We also considered using the percentage of MA rebate dollars allocated to buy down Parts A and B cost sharing compared to other supplemental benefits—D–SNP look-alikes typically allocate a greater percentage to the latter—as a way to identify D–SNP look-alikes. However, we chose our proposal over these alternatives for multiple reasons. First, we are concerned that further regulating benefit design in this way could inadvertently diminish benefit flexibility that genuinely improves competition and choice, without necessarily being designed to undermine rules applicable to D–SNPs. For example, it is conceivable that future benefit designs would be precluded by any benefit and cost sharing criteria we established to eliminate D–SNP look-alikes, even if those benefit designs would not have drawn a high percentage of dually eligible individuals based on factors that we cannot currently foresee. Second, we determined that MA organizations could likely avoid any new limitations on benefit design through small tweaks to their benefit design or allocation of MA rebate dollars. Most importantly, we determined that the best indicator that a MA organization intends a plan to have exclusive or predominantly dually eligible enrollment is in the enrollment it projects in the bid and in the enrollment it actually achieves. Finally, we believe the criteria to identify D–SNP look-alikes should mirror the principal criterion that distinguishes D–SNPs from other MA plans in statute the ability to have enrollment that exclusively, or predominantly, consists of dual eligible individuals—which enables a D–SNP to integrate and coordinate the delivery of Medicaid services and necessitates the additional care coordination to meet the needs of this vulnerable population. We seek comment on whether these alternative criteria should be used instead of, or in addition to, the criteria we are

proposing for identifying D–SNP look-alikes and applying contracting prohibition.

III. Implementation of Several Opioid Provisions of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

A. Mandatory Drug Management Programs (DMPs) (§ 423.153)

1. Summary and Background of DMPs

The SUPPORT Act made changes to the requirements for Part D DMPs to enhance Part D sponsors' ability to reduce the abuse or misuse of opioid medications in their prescription drug benefit plans. CMS is proposing two corresponding changes to the Part D DMP provisions codified in § 423.153(f): (1) Requiring Part D sponsors to adopt DMPs with respect to a plan year on or after January 1, 2022, as required under section 2004 of the SUPPORT Act; and (2) requiring inclusion of Part D beneficiaries with a history of opioid-related overdose in sponsors' DMPs beginning January 1, 2021, as required under section 2006 of the SUPPORT Act. In addition, CMS is proposing an additional category of exempt beneficiaries, for example, those with sickle cell disease, from DMPs and proposing several technical clarifications to the DMP regulations, which are described in subsequent paragraphs.

CARA amended the Act and included new authority for the establishment of DMPs in Medicare Part D, effective on or after January 1, 2019. CMS established through notice and comment rulemaking a framework at § 423.153(f) under which Part D plan sponsors may establish a DMP for beneficiaries at-risk for prescription drug abuse, or ''at-risk beneficiaries'' (ARBs) (defined in § 423.100).

Under the DMPs in place today, CMS identifies ''potential at-risk beneficiaries'' (PARBs) (defined in § 423.100) who meet the clinical guidelines described in § 423.153(f)(16), which we refer to as the minimum Overutilization Management System (OMS) criteria. The OMS reports such beneficiaries to their Part D plans for case management under their DMP. There are also supplemental clinical guidelines, or supplemental OMS criteria, which Part D sponsors can apply themselves to identify additional potential at-risk beneficiaries.

The OMS criteria used to identify PARBs are based on a history of filling opioids from multiple doctors and/or multiple pharmacies. Once PARBs are identified, plan sponsors engage in case management of these beneficiaries through contact with their prescribers to determine whether the beneficiary is at-risk for prescription drug misuse or abuse. If a sponsor determines through case management that a PARB is at-risk, after notifying the beneficiary in writing, the sponsor may limit their access to coverage of opioids and/or benzodiazepines to a selected prescriber and/or network pharmacy(ies) and/or through a beneficiary-specific point-of-sale (POS) claim edit. This process does not apply to ''exempted beneficiaries'' (defined at § 423.100). Exempted beneficiaries currently include those being treated for active cancer-related pain, residing in a long-term care facility, receiving hospice care or receiving palliative or end-of-life care, but we are proposing, in section VIII.N. of this proposed rule, to exempt beneficiaries with sickle cell disease beginning with plan year 2021.

CMS data has shown value from plan sponsors engaging in case management. From 2011 [26] through 2017, there was a 76 percent decrease in the number of Part D potential at-risk beneficiaries (almost 22,500 beneficiaries) who met the applicable OMS criteria under the prior opioid overutilization policy. Part D sponsors also implemented 4,375 beneficiary-specific POS opioid claim edits through 2017. Early analysis of the coverage limitations (for example, pharmacy and prescriber limitations and beneficiary-specific POS claim edits) implemented under DMPs through the second quarter of 2019 continues to show a relatively low application of coverage limitations by Part D sponsors. However, this is not unexpected,[27] as the design of the DMP process is for Part D sponsors to engage in beneficiary-specific casework with the PARB's prescribing physicians to address the unique needs of the beneficiary and coordinate care. Nevertheless, the availability and use of coverage limitations by sponsors remains important, necessary, and appropriate in certain clinical situations.

2. Mandatory Drug Management Programs (DMPs)

Section 2004 of the SUPPORT Act requires that, no later than January 1, 2022, Part D sponsors must have established DMPs. We are proposing to amend regulatory language at § 423.153(f) to reflect this requirement. We note that while implementation of DMPs has been optional since 2019, when Part D sponsors could first adopt them, 85.9 percent of Part D contracts in calendar year 2019 and 87.2 percent for calendar year 2020 adopted DMPs to address opioid overutilization among their enrollees. Thus, of about 49 million beneficiaries who were enrolled in the Medicare Part D program in 2019, about 48.5 million enrollees (99 percent) were covered under Part D contracts that offered a DMP already. Our internal analysis estimates that only 158 additional PARBs will be identified due to making DMPs mandatory by meeting the current minimum OMS criteria.

B. Beneficiaries With History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)

Under section 2006 of the SUPPORT Act, CMS is required to identify Part D beneficiaries with a history of opioid-related overdose (as defined by the Secretary), and such individuals must be included as PARBs for prescription drug abuse under a Part D plan's DMP. CMS is also required under this section to notify the sponsor of such identifications. In line with this requirement, we are proposing to modify the definition of ''potential at-risk beneficiary'' at § 423.100 to include a Part D eligible individual who is identified as having a history of opioid-related overdose, as we propose to define it.

We propose to define ''history of opioid-related overdose'' to mean that for the Part D beneficiary, a recent claim has been submitted [28] that contains a principal diagnosis code reflecting an opioid overdose, regardless of the type of opioid and at least one recent PDE for an opioid dispensed to such beneficiary has been submitted.

We propose to operationalize this proposed definition by: (1) Using diagnoses that include both prescription and illicit opioid overdoses; (2) using a 12-month lookback period from the end of each OMS reporting quarter, for record of opioid-related overdose within Medicare fee-for-service (FFS) claims

[26] In developing the Medicare Part D opioid overutilization policy and OMS which began in 2013, we conducted pilots and testing in 2012. Therefore, we use 2011 as the pre-pilot/pre-policy measurement period. DMPs incorporated the OMS criteria and case management approach established in the opioid overutilization policy.

[27] See discussion p. 16690: ICRs Regarding the Implementation of the Comprehensive Addictions and Recovery Act of 2018 (CARA) Provisions (§ 423.153) in the April 2018 final rule (83 FR 16440).

[28] Claim date for meeting lookback period criteria based on the claim dates of service, admission date or date the claim was loaded into CMS's data warehouse.

and Medicare Advantage Encounter data (excluding those not enrolled in a Part D plan, whether an MA–PD or standalone PDP plan); and (3) using a 6-month lookback period from the end of each OMS reporting quarter, for record of a recent Part D opioid PDE. The number of unique beneficiaries identified under this proposal is approximately 18,268.

Our rationale for this proposal is that a past overdose is the risk factor most predictive for another overdose or suicide-related event.[29] We propose using diagnoses that include both prescription and illicit opioid overdoses because an opioid overdose may result from prescription or illicit opioids alone or in combination, and the statute does not distinguish based on type of opioid. Further, in the case of prescription opioids, the diagnosis code does not indicate if the prescription was legally obtained and used by the intended patient. Lastly, we propose to define history of opioid-related overdose to include only those instances where the enrollee also recently filled an opioid prescription under their Part D benefit, because the existence of an opioid PDE means sponsors would have an opioid prescriber with whom to conduct case management, which is an integral part of the DMP process.

Other factors we took into consideration for our proposal: First, as to including both prescription and illicit opioid overdose diagnoses, we considered that the Part D program is a prescription drug benefit program and, therefore, considered defining a history of opioid-related overdose as only including those overdoses involving validly prescribed and taken prescription opioids. However, given the risks associated with opioid-related overdose, we believe the best policy is to include both types of overdoses. Also, we cannot accurately identify whether an illicit or prescription opioid drug or drugs contributed to an overdose, and even if we could, we cannot determine whether a prescription opioid that contributed to the overdose was legally obtained and taken. Thus, our approach also overcomes limitations in the diagnosis data available (described further in this section of this proposed rule). The Alternatives Considered section of the Regulatory Impact Analysis (section X.D.1. of this proposed rule) provides a more in-depth review of the various other approaches considered and the projected numbers of affected enrollees.

Second, we note that the proposed 12-month lookback period of Medicare FFS claims and Medicare Advantage Encounter data to identify enrollees with a history of opioid-related overdose, which aligns with the measurement period used for active cancer diagnosis data in the current OMS criteria, takes into account program size and factors in patterns of beneficiaries who overdose more than once. We think 12 months is the appropriate lookback period to identify the beneficiaries who are at the most risk. When using Medicare fee-for-service inpatient data, we noted that a two-year lookback period (between July 2016 and June 2018) for Medicare beneficiaries who overdosed more than once almost proportionately doubles the number of overdoses compared to a one-year lookback (July 2017 to June 2018); however, 90 percent of the beneficiaries who had more than one opioid-related overdose episode, had a subsequent overdose episode on average within 12 months. In our methodology, we used the calendar month and year of opioid-related overdose events to identify each episode and also found that 95 percent of the beneficiaries had a subsequent overdose episode on average within 14 months and 99 percent of the beneficiaries had a subsequent overdose episode on average within 19 months. Thus, a 12-month lookback period strikes a better balance in identifying beneficiaries who would be at risk of having another opioid-related overdose taking into consideration the drug management program size.

Third, while we considered reporting any enrollees who have a history of opioid-related overdose during the 12-month lookback period, regardless of whether there is an opioid PDE, we believe our proposal to report only those enrollees who also recently filled a Part D opioid prescription should increase the likelihood for the sponsor to conduct successful provider outreach for case management. This aligns with the 6-month measurement period used for opioid PDE records in the current OMS criteria. We solicit feedback on the proposed 12-month lookback period for identifying claims for opioid-related overdose and the proposal to report only those enrollees with at least one Part D opioid PDE within the prior 6 months.

To derive an estimated population of PARBs identified under this proposal, we identified beneficiaries with inpatient, outpatient or professional FFS or encounter data opioid overdose claims based on the principal International Classification of Disease (ICD)-10 diagnosis codes (see Table 1) during the 12-month measurement period from 07/01/2017 to 06/30/2018 and at least one recent Part D opioid PDE from 01/01/2018 to 06/30/2018. We excluded beneficiaries if they were identified as having elected hospice, in a resident facility, had palliative care diagnosis, and/or had a death date during the last 6 months (01/01/2018–06/30/2018). We also excluded beneficiaries if they had active cancer during the 12-month lookback period (07/01/2017–06/30/2018). This is consistent with the measurement period used to identify these attributes in the current OMS criteria. Finally, we excluded beneficiaries who were not Part D enrolled during the last month of the OMS measurement period. Again, the number of unique beneficiaries identified under this proposal is 18,268. To align with our current OMS quarterly reporting frequency, we ran additional simulations using 2018 data and estimated that about 4,500 new beneficiaries with an opioid related overdose would be identified every quarter.

TABLE 1—LIST OF OPIOID-RELATED OVERDOSE CODES INCLUDED IN ANALYSIS

Overdose type	ICD–10 diagnosis codes [30]
Any Opioid	T40.0 (opium), T40.1 (heroin), T40.2 (natural/semisynthetic opioids including hydrocodone and oxycodone), T40.3 (methadone), T40.4 (synthetic opioids other methadone including fentanyl and tramadol) and T40.6 (other and unspecified narcotics).
Prescription Opioid	T40.2 (natural/semisynthetic opioids including hydrocodone and oxycodone), T40.3 (methadone), and T40.6 (other and unspecified narcotics).
Illicit Opioid	T40.1 (heroin) and T40.4 (synthetic opioids other methadone likely illicitly manufactured fentanyl).

[29] Bohnert KM, Ilgen MA, Louzon S, McCarthy JF, Katz IR. Substance use disorders and the risk of suicide mortality among men and women in the US Veterans Health Administration. Addiction. 2017 Jul;112(7):1193–1201. doi: 10.1111/add.13774.

[30] ICD–10 diagnosis codes related to underdosing, adverse effects and assault are excluded.

Table 1 categorizes the diagnoses codes we used to derive our estimate, as well as the other options in section X.D.1. of this proposed rule. As previously noted, there are limitations when using diagnosis data to identify opioid-related overdoses. An additional limitation is that there is an unspecified opioid overdose code, which requires that assumptions be made in order to classify an overdose code as prescription or illicit. We classified code 40.2 (other opioids), as a prescription opioid overdose, but in some cases oxycodone may have been obtained illegally. We classified code 40.4 (other synthetic opioids) as illicit opioid overdose but in some cases fentanyl may have been obtained by prescription. We made these designations in order for our proposal to align with Centers for Disease Control and Prevention's (CDC) practice of defining all fentanyl overdoses (synthetic opioids other than methadone) as likely illicit.[31]

As noted earlier in this proposed rule, Part D sponsors with DMPs must conduct case management for each PARB identified by CMS through OMS which includes sending written information to the beneficiary's prescribers that the beneficiary met the clinical guidelines/OMS criteria and is a PARB. Currently, case management under DMPs generally addresses safety concerns related to opioid prescriptions for Part D beneficiaries involving multiple prescribers/pharmacies. We continue to encourage providers to consult state-based prescription drug monitoring programs before prescribing opioids to reduce the number of beneficiaries meeting the current OMS criteria. However, under this proposal, the nature of the safety concern for the Part D beneficiaries who must be identified and reported to sponsors by OMS is different. Sponsors will communicate with providers about potential safety concerns due to the beneficiary's history of opioid-related overdose, and the provider may or may not already be aware of this history and the beneficiary may or may not be using multiple opioid prescribers/pharmacies. Thus, our proposal is similar to PARBs who are reported by OMS with a benzodiazepine flag, as a particular provider may or may not be aware that a beneficiary is taking benzodiazepines in addition to opioids.

Such communication is an opportunity for sponsors, through their DMPs, to offer information to, and/or discuss with, providers the risk factors relevant to opioid use and a prior overdose history, and to make prescribers aware of the tools available under a DMP to assist them in managing their patient's care, as they consider prescription opioid use of their patient. The provider should also consider prescribing the beneficiary an opioid-reversal agent if they are newly aware of the beneficiary's history of opioid-related overdose and DMPs should notify providers and patients of the coverage of naloxone and its availability through their plan. As with any beneficiary in a DMP, the goal is the best-possible, coordinated, and safe care for each unique patient as determined by their provider(s), and not to stigmatize the patient; nor abruptly taper or discontinue their medications, nor unnecessarily or abruptly remove the patient from a provider's practice.

We solicit comments on whether our proposal needs any additional features to facilitate the case management process for PARBs with a history of opioid related overdose, such as written sponsor-provider communication and/or to address the anticipated effects of this type of sponsor-provider collaboration. We recognize that the model beneficiary notices[32] provided by CMS may need to be revised to incorporate a PARB having a history of opioid-related overdose (noted in section IX.B.3. of this proposed rule).

C. Information on the Safe Disposal of Prescription Drugs (§ 422.111)

Section 6103 of the SUPPORT Act amends section 1852 of the Act by adding a new subsection (n). Section 1852(n)(1) requires MA plans to provide information on the safe disposal of prescription drugs when furnishing an in-home health risk assessment. Section 1852(n)(2) requires us to establish, through rulemaking, criteria that we determine appropriate with respect to information provided to an individual during an in-home health risk assessment to ensure that he or she is sufficiently educated on the safe disposal of prescription drugs that are controlled substances.

In order to implement the requirements of section 1852(n)(1) for MA plans, CMS proposes to revise the § 422.111, Disclosure Requirements, to add a paragraph (j), which would require MA plans that furnish an in-home health risk assessment on or after January 1, 2021, to include both verbal (when possible) and written information on the safe disposal of prescription drugs that are controlled substances in such assessment. Consistent with section 1852(n)(1), we propose that information must include details on drug takeback programs and safe in-home disposal methods.

In educating beneficiaries about the safe disposal of medications that are controlled substances, we propose MA plans would communicate to beneficiaries in writing and, when feasible, verbally. We propose that MA plans must do the following to ensure that the individual is sufficiently educated on the safe disposal of controlled substances: (1) Advise the enrollee that unused medications should be disposed of as soon as possible; (2) advise the enrollee that the US Drug Enforcement Administration allows unused prescription medications to be mailed back to pharmacies or other authorized sites using packages made available at such pharmacies or other authorized sites; (3) advise the enrollee that the preferred method of disposing of controlled substances is to bring them to a drug take back site; (4) identify drug take back sites that are within the enrollee's MA plan service area or that are nearest to the enrollee's residence; and (5) instruct the enrollee on the safe disposal of medications that can be discarded in the household trash or safely flushed. Although we are not proposing to require MA plans to provide more specific instructions with respect to drug disposal, we are proposing that the communication to enrollees provide the following additional guidance: If a drug can be safely disposed of in the enrollee's home, the enrollee should conceal or remove any personal information, including Rx number, on any empty medication containers. If a drug can be discarded in the trash, the enrollee should mix the drugs with an undesirable substance such as dirt or used coffee grounds, place the mixture in a sealed container such as an empty margarine tub, and discard in the trash.

We also propose that the written communication include a web link to the information available on the United States Department of Health and Human Services website identifying methods for the safe disposal of drugs available at the following address: *https://www.hhs.gov/opioids/prevention/safely-dispose-drugs/index.html.* We note that the safe disposal of drugs guidance at this website can be used for all medications not just medications that

[31] Current information reported about overdose deaths in NVSS does not distinguish pharmaceutical fentanyl from illicitly manufactured fentanyl (IMF). Opioid Data Analysis and Resources. Available from: *https://www.cdc.gov/drugoverdose/data/analysis.html.*

[32] Notice documents available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Drug-Management-Program-Notices-.zip.*

are controlled substances. We believe that plan communications consistent with the standard on this website provides enrollees with sufficient information for proper disposal of controlled substances in their community.

D. Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)

Sponsors of Part D prescription drug plans, including MA–PDs and standalone PDPs, must disclose certain information about their Part D plans to each enrollee in a clear, accurate, and standardized form at the time of enrollment and at least annually thereafter under section 1860D–4(a)(1)(a) of the Act. Among the drug specific information that sponsors must provide pursuant to section 1860D–4(a)(1)(B) of the Act is information about the plan formulary, pharmacy networks, beneficiary cost-sharing requirements, and the availability of medication therapy management (MTM) and DMPs.

Section 6102 of the SUPPORT Act amended section 1860D–4(a)(1)(B) of the Act to require that, for plan year 2021 and each subsequent plan year, Part D sponsors also must disclose to each enrollee, with respect to the treatment of pain, information about the risks of prolonged opioid use. In addition to this information, with respect to the treatment of pain, MA–PD sponsors must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans. Sponsors of standalone PDPs must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans and under Medicare Parts A and B.

Section 6102 of the SUPPORT Act also amended section 1860D–4(a)(1)(C) of the Act to permit Part D sponsors to disclose this opioid risk and alternative treatment coverage information to only a subset of plan enrollees, such as enrollees who have been prescribed an opioid in the previous 2-year period, rather than disclosing the information to each plan enrollee. To implement section 6102, we propose to amend our regulations at § 423.128 to reflect that Part D sponsors may provide such information to a subset of such enrollees, in accordance with section 1860D–4(a)(1)(C), in lieu of providing it to all enrollees.

If a sponsor does not send the information to all enrollees, we have a few suggested subsets of enrollees for sponsors to consider and the estimated number of enrollees in each subset, as shown in Table 2. The estimates are based on 2018 Part D PDE data and do not include the populations that are exempted from Part D opioid policies in 2021, for example, enrollees with active cancer-related pain, in hospice, in a resident facility, or in palliative care. Sponsors may or may not choose to adopt one of the suggestions, and sponsors may or may not exempt the same beneficiaries that are exempted from other Part D opioid policies.

However, we thought that providing some options, along with Part D program-wide data, would be useful to sponsors, as they decide to which enrollees they will disclose the required opioid risk and alternate pain treatment coverage information. We are also interested in comments identifying other possible appropriate subsets of enrollees.

TABLE 2—SUGGESTED SUBSET OPTIONS TO RECEIVE EDUCATION ON OPIOID RISKS AND ALTERNATE TREATMENTS *

Subset	Suggested subset	Number of enrollees in this subset	Percent of total opioid users
1	All Part D Enrollees	46,759,911	N/A
2	Any opioid use in last 2 years	16,134,063	100
3	Any opioid use in past year	11,027,271	100
4	7 days continuous opioid use	7,163,615	65
5	Greater than 30 days continuous opioid use, 7 day or less gap	3,816,731	35
6	Greater than 90 days continuous opioid use, 7 day or less gap	2,698,064	24

* All figures based on 2018 PDE data as of 7/6/2019, except subset 2 which is based on 2017 and 2018 PDE data. Beneficiaries were excluded from the opioid use subsets if they were in hospice, in a resident facility, or had a palliative care diagnosis (07/01/2018–12/31/2018). Beneficiaries were also excluded if they had a cancer diagnosis (01/01/2018–12/31/2018). No exclusions were applied to the all Part D enrollees figure (subset 1).

The first suggested option is for sponsors to disclose the opioid risk and alternate coverage information to all Part D enrollees. This option has the advantage of disseminating the information most widely—to approximately 46,759,911 enrollees—and not trying to determine which enrollees may need the information more than other enrollees. Beneficiaries may receive information about risks and treatment alternatives before they use opioids under this option. However, this option has the disadvantage of being largely over-inclusive, in the sense that a significant number of enrollees will receive information that is not, and may never be, pertinent to them.

The second suggested option is to disclose the opioid information to the subset suggested by the SUPPORT Act, which is enrollees who have been prescribed an opioid in the previous 2-year period, approximately 16,134,063 enrollees. This option has the advantage of targeting enrollees who have actually used opioids, but has the disadvantage of not being as proactive as the first option, while also still including enrollees who may not have used opioids in quite some time; may only have used them for short-term acute use; and may not take them again soon or ever.

The third suggestion option is to disclose the opioid information to the subset of all opioid users in the Part D program who had at least one opioid prescription in a year, which would be 11,027,271 enrollees based on 2018 estimates. This option still has the advantage of a fairly wide dissemination of information about the risk of opioid use and coverage of alternate pain treatment; however, it would also mean that the information would be sent to enrollees who only took opioids for short-term acute use; are no longer taking opioids; or may never take them again.

The fourth suggested option is to disclose the opioid information to the subset of enrollees who have a greater than 7 days of continued opioid use. This option would disseminate the information to 7,163,615 enrollees, who represent well over the majority (65%) of opioid users in the Part D program. While this subset is much more targeted than the other suggested subsets, it would involve sending the information to enrollees who may still be in the acute phase of opioid use and may not

transition to chronic use, as three-quarters of opioids users in 2018 had less than 90 days of opioid use. Moreover, our internal analysis shows that opioid prescriptions are filled with a median day supply of 30 days. Thus, the greater than 7 day use criteria would include enrollees who have not yet received a subsequent opioid fill after an initial opioid prescription or received fills with a smaller days' supply.

A fifth suggested option is to disclose this information to the subset of enrollees with greater than 30 days of continuous opioid use without more than a 7 day gap. This subset would be approximately 3,816,731 enrollees, which is 35% of opioid users. This suggested option attempts to strike a balance of not sending the information to enrollees who are less at risk for prolonged opioid use and to proactively educate enrollees who could be at risk before progression to chronic opioid use. However, no option can precisely distinguish between enrollees who will only use opioids for an acute period and those who will progress to chronic use, putting them at greater risk of complications. Of note, this option does not account for providing the information before the enrollee begins opioid use.

A sixth and final suggested option is to disclose this information to the subset of enrollees with greater than greater than 90 days continuous opioid use, without more than a 7 day gap. This option involves approximately 2,698,064 enrollees which represent 24% of opioid users in the Part D program. While this option involves the smallest number of Part D enrollees, it has the disadvantage that the information will be disclosed to enrollees who are more likely already chronic users of opioids. While the information may still be useful to them if they are concerned about the risks of opioids and interested in alternate treatments, this option would not have a proactive aspect for enrollees who are not yet chronic opioid users.

For these suggested options, we note that we considered opioid use to be ''continuous'' even if there is a short break, such as 7 days or fewer, in opioid utilization. To illustrate our suggested approach, if a beneficiary filled an opioid prescription on 01/01/2018 for a 5 day supply and another on 01/10/2018 for a 10 days, this beneficiary would have a continuous opioid use days of 20 days ==that is a 5 days + 10 days + 5 ''gap days.'' This approach would not take into account early refills, but rather allow up to a 7 days gap period to accommodate for varying prescription refills and beneficiary opioid utilization patterns.

Section 1860D–4(a)(1)(C) also permits Part D sponsors to disclose the required information to enrollees through mail or electronic means. Given the importance of the information, we suggest that sponsors only send it electronically if the enrollee has consented to receiving plan information in electronic form.

The existing regulatory framework for the information that must be disclosed pursuant to section 1860D–4(a)(1) of the Act is § 423.128. CMS proposes to use this existing regulatory framework to codify the opioid risk and alternative pain treatment coverage information that Part D sponsors must disseminate pursuant to section 6102 of the SUPPORT Act. Specifically, CMS proposes to revise § 423.128(a) to provide that, except as provided in new paragraph (b)(11), information specified in paragraph (b) must be provided to each enrollee annually in a clear, accurate, and standardized form. We propose in new paragraph (b)(11) that the plan would be required to disclose to each enrollee, with respect to the treatment of pain, the risks associated with prolonged opioid use and coverage of alternative therapies, unless the plan elects to provide such information to a subset of enrollees, as discussed previously.

To assist Part D sponsors in providing clear and accurate information to enrollees, we refer MA–PDs and standalone PDPs to CMS' pain management website (*https://www.medicare.gov/coverage/pain-management*), which contains coverage information on non-pharmacological therapies, devices, and non-opioid medications for the treatment of pain under the Medicare fee-for-service program. Part D sponsors would be able to be use this information to convey the required alternative treatment coverage information MA–PD sponsors can consult this website as well, however, they would also be required to add any additional coverage that they provide under their plans to their standardized forms. We believe that both MA–PDs and standalone PDPs should be able to describe the risks of prolonged opioid use, as they both provide drug coverage and thus have expertise in the use of drugs. However, we refer Part D sponsors to the U.S. Department of Health and Human Services website as an additional resource that contains information about the risks of opioids, as well as a searchable index for local treatment centers addressing substance abuse and mental health consultations. (See *https://www.hhs.gov/opioids/*)

E. Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153)

We propose to amend Part D Medication Therapy Management (MTM) program requirements in § 423.153 to conform with the relevant SUPPORT Act provisions. The SUPPORT Act modified MTM program requirements for Medicare Part D plans beginning January 1, 2021, by expanding the population of beneficiaries who are targeted for MTM program enrollment (''targeted beneficiaries'') to include at-risk beneficiaries (ARBs), and by adding a new service component requirement for all targeted beneficiaries. More specifically, first, section 6064 of the SUPPORT Act amended section 1860D–4(c)(2)(A)(ii) of the Act by adding a new provision requiring that ARBs be targeted for enrollment in the Part D plan's MTM program. Our proposal to implement this provision would be codified at § 423.153(d)(2). Second, section 6103 of the SUPPORT Act amended the MTM program requirements in section 1860D–4(c)(2)(B) of the Act by requiring Part D plans to provide enrollees with information about the safe disposal of prescription drugs that are controlled substances, including information on drug takeback programs, in-home disposal, and cost-effective means for safe disposal of such drugs. Our proposal to implement this provision would be codified at § 423.153(d)(1)(vii)(E).

We wish to provide some background on Part D MTM programs before further delineating our proposal to revise the definition of ''targeted beneficiaries'' for purposes of MTM to include beneficiaries who are determined to be at-risk beneficiaries (ARBs) under Part D sponsors' drug management programs (DMPs), meaning beneficiaries who are at-risk for prescription drug abuse. Please refer to sections III.A. and III.B. of this proposed rule for more information about DMPs.

MTM programs serve as integral components of the Medicare Part D benefit. All Part D sponsors are required to have an MTM program that is designed to assure, with respect to targeted beneficiaries, that covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions (see section 1860D–4(c)(2)). The Act also establishes general patient eligibility and service intervention requirements that CMS has implemented through regulation in

§ 423.153(d). Each Part D sponsor has the latitude to develop specific eligibility criteria for its own MTM program, as long as the criteria target beneficiaries who: (1) Have multiple chronic diseases, with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment; (2) are taking multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment; and (3) are likely to incur costs for covered Part D drugs in an amount greater than or equal to the specified cost threshold ($4,255 for plan year 2020). The MTM cost threshold is increased each year by the annual percentage specified in § 423.104(d)(5)(iv). CMS reviews Part D sponsor submissions to ensure compliance with MTM requirements. Section 423.153(d)(6) requires each Part D sponsor to provide information regarding the procedures and performance of its MTM program to CMS for review.

1. ARBs and MTM

As part of codifying the framework for DMPs in 2018, CMS codified a definition of an ARB in § 423.100. An ARB is defined as a Part D eligible individual—(1) who is—(i) Identified using clinical guidelines (as defined in § 423.100); (ii) Not an exempted beneficiary; and (iii) Determined to be at-risk for misuse or abuse of such frequently abused drugs (FADs) under a Part D sponsor's drug management program in accordance with the requirements of § 423.153(f); or (2) With respect to whom a Part D sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as an at-risk beneficiary (as defined in the paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon disenrollment. Please refer to sections III.A. and III.B. of this proposed rule for more information about DMPs.

Under our proposed revisions to § 423.153(d) to implement sections 6064 and 6103 of the SUPPORT Act, at-risk beneficiaries, as defined in § 423.100 would be targeted for enrollment in a sponsor's MTM program. The existing criteria that Part D sponsors currently use to target beneficiaries for MTM program enrollment would remain unchanged, so that two groups of enrollees would now be targeted for enrollment: the first group would include enrollees who meet the existing criteria (multiple chronic diseases, multiple Part D drugs and Part D drug costs); and the second group would include enrollees who are determined to be at-risk beneficiaries under § 423.100. The MTM program requirements would be the same for all targeted beneficiaries enrolled in a Part D sponsor's MTM program, regardless of whether they were targeted for enrollment based upon the existing criteria or because they are at-risk beneficiaries.

Under this proposal, Part D sponsors would be required to automatically enroll all at-risk beneficiaries in their MTM programs on an opt-out only basis as required in § 423.153(d)(1)(v). In addition, Part D sponsors would be required to offer each at-risk beneficiary enrolled in the MTM program the same minimum level of MTM services as specified in § 423.153(d)(1)(vii) that sponsors currently are required to offer to beneficiaries enrolled in their MTM program.

This means, in addition to interventions for both beneficiaries and prescribers, sponsors must offer ARBs an annual comprehensive medication review (CMR) under § 423.153(d)(1)(vii)(B). By way of background, CMS has developed a Standardized Format that an MTM provider must use to summarize the results of the CMR and recommended action plan for the beneficiary (reference CMS–10396, OMB Control Number 0938–1154). The CMR must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider. Section 423.153(d)(1)(vii)(B)(*2*) provides that in the event the beneficiary is offered the annual CMR and is unable to accept the offer to participate, the MTM provider may reach out to the beneficiary's prescriber, caregiver, or other authorized individual. The CMS Standardized Format provides instructions for those circumstances. In the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes; Final Rule (77 FR 22140), we explained that when the beneficiary is cognitively impaired and cannot make decisions regarding his or her medical needs (that is, is unable to accept the offer to participate), we recommend that the pharmacist or qualified provider reach out to the beneficiary's prescriber, caregiver, or other authorized individual, such as the resident's health care proxy or legal guardian, to take part in the beneficiary's CMR. However, this recommendation applies only to those situations where fulfilment of that statutory obligation is not reasonably possible because the beneficiary is cognitively impaired; it does not apply to situations where the sponsor is unable to reach the beneficiary (such as no response by mail, no response after one or more phone attempts, or lack of phone number or address), if there is no evidence of cognitive impairment, or the beneficiary declines the CMR offer. When the CMR is performed with an authorized individual participating on the beneficiary's behalf, the MTM provider should discuss the delivery of the CMS Standardized Format and any accompanying summary materials with the beneficiary's representative to determine to whom and where they should be sent. The CMR summary should be delivered to the beneficiary's authorized representative, such as the health care power of attorney or the enrollee's representative.[33] Currently, the CMS Standardized Format is not in a machine-readable format because it is designed for sharing with the beneficiary, although the MTM provider may elect to share the information with the beneficiary's provider as well.

In addition to the CMR, the minimum level of MTM services also includes a requirement at § 423.153(d)(1)(vii)(C) for the plan to provide targeted medication reviews (TMRs) to all MTM program enrollees no less often than quarterly following MTM enrollment with follow-up interventions when necessary. Thus, under our proposal, Part D sponsors would have to provide TMRs to ARBs enrolled in their MTM program. As additional background, CMS has not provided a standardized format for the TMR service, and the MTM provider should determine the patient's unmet medication-related needs and use the TMR to follow up with the patient (or prescriber) as appropriate. The follow-up interventions with MTM-enrolled beneficiaries should be person-to-person, if possible, but may be delivered via the mail or other means. Sponsors may determine how to tailor the follow-up interventions based on the specific needs or medication use issues of the beneficiary. The MTM provider should seek to resolve any recurring issues that exist with the patient, as well as to identify any new opportunities that are identified. Therefore, while the follow-up intervention that results from a TMR may be person-to-person, the TMR is distinct from a CMR because the TMR is focused on specific actual or potential medication-related problems (see

[33] See Standardized Format FAQ: *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MTM-Program-Standardized-Format-Revisions-v082917.zip.*

annual MTM Program guidance memo).[34]

Like all other targeted beneficiaries, ARBs would be required to be enrolled in the Part D sponsor's MTM program using an opt-out method of enrollment.[35] As explained in the MTM Program guidance memo, following enrollment in the MTM program, a beneficiary may refuse or decline individual services without having to disenroll from the program. For example, if an enrolled ARB declines the annual CMR, § 423.153(d)(1)(vii)(C) still requires the sponsor to offer interventions to the prescriber and perform TMRs at least quarterly to assess medication use on an on-going basis. In addition, sponsors should not wait for the beneficiary to accept the offer for the CMR and should perform TMRs and provide interventions to the beneficiary's prescriber once the beneficiary is enrolled in the MTM program. Part D sponsors are encouraged to use more than one approach when possible to reach all eligible targeted beneficiaries to offer MTM services versus only reaching out via passive offers. Sponsors may increase beneficiary engagement by following up with beneficiaries who do not respond to initial offers (for example, by providing telephonic outreach after mailed outreach). Also, sponsors are expected to put in place safeguards against discrimination based on the nature of their MTM interventions (for example, using TTY if phone based, Braille if mail based, etc.).

Including ARBs in Part D MTM programs as proposed would provide Part D sponsors with another tool to address opioid misuse among the Part D beneficiaries they serve. DMPs primarily involve a prescriber-centric approach through case management to promote safer use of opioids and benzodiazepines and care coordination. In contrast, MTM leverages a beneficiary-centric approach to improve the beneficiary's medication use and reduce the risk of adverse events involving all of the medications the beneficiary is taking (including opioids and other FADs). We encourage sponsors to design MTM interventions for this new population of targeted beneficiaries to reflect their simultaneous inclusion in the sponsors' DMPs. For example, MTM services for these beneficiaries may include beneficiary and/or prescriber interventions or discussions to assess the risks and benefits of ongoing opioid use, discuss beneficiary goals and alternative treatment options, talk about how to prevent prescription drug misuse and overdose, review access to naloxone, assess concurrent use of benzodiazepines or other potentiator drugs that may increase the risk for adverse events or overdose, review common side effects, and discuss safe storage and safe disposal of medications. (As noted later in this section, beginning in 2021, MTM services furnished to all targeted beneficiaries must include the provision of certain information on the safe disposal of prescription drugs that are controlled substances.) We recommend that plans consult existing clinical guidelines, such as those issued by the Centers for Disease Control and Prevention for Prescribing Opioids for Chronic Pain,[36] when developing MTM strategies and materials. These materials may help plans design MTM interventions such that treatment decisions to start, stop or reduce prescription opioids are individualized and carefully considered between the prescriber and at-risk beneficiary. Interventions should not promote abrupt tapering or discontinuation of opioids.

Because we propose that beneficiaries would be targeted for MTM services on the basis of being an ARB, this means that the beneficiary will have received a second written notice in accordance with DMP regulations at § 423.153(f)(6). CMS solicits input into how sponsors can best coordinate DMPs and MTM programs and effectively perform outreach to offer MTM services. We also seek feedback on how to leverage MTM services to improve medication use and reduce the risk of adverse events in this population, how to measure the quality of MTM services delivered, and how to increase meaningful engagement of the new target population in MTM. Lastly, we seek comments on the type of information that CMS should use to monitor the impact of MTM services on at-risk beneficiaries, who will now be targeted for MTM services.

As the annual CMR is a key element of the MTM services, we have evaluated the CMS Standardized Format to determine how it might be modified in order to accommodate the new population of at-risk beneficiaries that will be enrolled in Part D sponsors' MTM programs. The Standardized Format for the CMR must be approved by the Office of Management and Budget (OMB) through the Paperwork Reduction Act (PRA) process. OMB has approved the current version of the standardized format (CMS–10396; OMB control number: 0938–1154) until August 31, 2020. Based on the results of feedback from limited cognitive interviews with consumers and other stakeholders conducted in 2018, we had intended to propose revisions to the Standardized Format to optimize the utility of the CMR summary for beneficiaries while reducing burden on Part D sponsors through a standalone PRA package approval process as we did when the Standardized Format was originally developed. However, the changes proposed in this proposed rule will also require changes to the Standardized Format for the CMR summary to account for information provided to MTM enrollees about the safe disposal of prescription medications that are controlled substances, as discussed later in this section. In order to allow Part D plans to review all proposed changes to the document together, in section IX.B.5. of this proposed rule we are proposing a new format for the Standardized Format and seeking public comment.

Also, we encourage sponsors to share the CMR summary with the beneficiaries' prescribers, including those the sponsor engaged in case management under DMPs, to help them coordinate care for these beneficiaries. In order to facilitate the transfer of information from the CMR to the Electronic Health Record (EHR), we are considering modifying the CMS Standardized Format to allow the form to be completed in a machine readable format. In the Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers Proposed Rule (84 FR 7610), CMS proposed a framework for the sharing of data across the industry, which we believe may be suitable to use when conveying data from the MTM provider to the prescriber. The policies in that proposed rule would encourage use of Health Level Seven (HL7®) Fast

[34] See Annual MTM Program Guidance Memo, April 5, 2019, CY 2020 Medication Therapy Management Program Guidance and Submission Instructions: *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Memo-Contract-Year-2020-Medication-Therapy-Management-MTM-Program-Submission-v-041019-.pdf.*

[35] See § 423.153(d)(1)(v).

[36] Accessible at *https://www.cdc.gov/mmwr/ volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm.*

Healthcare Interoperability Resources (FHIR®)-based APIs to make other health information more widely accessible. We are seeking feedback on whether using HL7®-enabled CMRs could positively impact the sharing of CMR data with the prescriber for an MTM enrollee. We also seek input on the value of encouraging Part D MTM providers to use FHIR-enabled platforms when providing MTM to Part D enrollees to facilitate integration of the MTM service elements into prescribers' EHRs.

2. Information on Safe Disposal of Prescription Drugs That Are Controlled Substances for MTM Enrollees

The information we previously provided about CMRs and TMRs is also relevant to our proposal to implement Section 6103 of the SUPPORT Act, which, as we described at the beginning of this section, amended the MTM requirements in section 1860D–4(c)(2)(B) of the Act. Section 6103 added a new requirement that Part D plans provide beneficiaries enrolled in their MTM program with information about the safe disposal of prescription drugs that are controlled substances, including information on drug takeback programs, in-home disposal, and cost-effective means for safe disposal of such drugs. To implement this new requirement, we propose that Part D sponsors would be required to provide this information to all beneficiaries enrolled in their MTM programs at least annually, as part of the CMR or through the quarterly TMRs or follow up. Furthermore, while not required, we encourage sponsors to provide information on safe disposal of all medications, not just controlled substances, to MTM enrollees.

Section 6103 of the SUPPORT Act states that the information provided to beneficiaries regarding safe disposal of prescription drugs that are controlled substances must meet the criteria established in section 1852(n)(2) of the Act, including information on drug takeback programs that meet such requirements determined appropriate by the Secretary and information on in-home disposal. Section 1852(n)(2) states that the Secretary shall, through rulemaking, establish criteria the Secretary determines appropriate to ensure that the information provided to an individual sufficiently educates the individual on the safe disposal of prescription drugs that are controlled substances. We describe our proposed criteria and requirements for MA plans to furnish information on safe disposal of controlled substances when providing an in-home health risk assessment in section III.C. of this proposed rule and propose to codify these requirements in a new provision of the regulations at § 422.111(j); in this section we are proposing that Part D plans would be required to furnish materials in their MTM programs regarding safe disposal of prescription drugs that are controlled substances that meet the criteria specified in § 422.111(j). Like MA plans, Part D plans would retain the flexibility to refine their educational materials based on updated information and/or on beneficiary feedback, so long as the materials meet the proposed criteria. Section 1860D–4(c)(2)(B)(ii) expressly directs that the information on safe disposal furnished as part of an MTM program meet the criteria established under section 1852(n)(2) for MA plans. Accordingly, to ensure consistency and to avoid burdening MA–PD plans with creating separate documents addressing safe disposal for purposes of conducting in-home health risk assessments and their MTM programs, CMS believes it is appropriate to apply the same criteria specified in the proposed provision at § 422.111(j) to MTM programs by including a reference to the requirements of § 422.111(j) in the regulation at § 423.153(d) governing MTM programs.

When developing the proposal to codify section 6103 of the SUPPORT Act, we considered proposing to require that safe disposal be addressed during the CMR session. Because the required information would appear to be a natural topic of interest when reviewing a beneficiary's medication history; the MTM provider could provide information in the medication action plan section of the CMR summary on drug takeback programs and safe in-home disposal methods, as required by the SUPPORT Act. This would allow the beneficiary to have all pertinent reference materials within the Standardized Format and also avoid the MTM provider having to mail a separate document to the beneficiary.

However, granting MTM providers the flexibility to furnish safe disposal information to MTM recipients during the CMR session, as part of a quarterly TMR, or through another follow-up service could have significant advantages over requiring that the information be provided during the CMR session. For example, beneficiaries may decline the CMR, which would result in their not receiving safe disposal information as required. On the other hand, quarterly TMRs are performed for all eligible enrollees, meaning that safe disposal information could be circulated to all eligible beneficiaries, not just those who accept the CMR service. In the event that a beneficiary does not receive a CMR that includes safe disposal information, the plan would need to ensure that a TMR that includes safe disposal information is provided to the beneficiary either in person (such as at the pharmacy) or by mail. Additionally, as plan sponsors begin quarterly TMRs immediately upon enrolling a beneficiary in the MTM program, beneficiaries could receive this important information soon after qualifying for MTM rather than waiting for a CMR to be scheduled. Based on these considerations, we propose to give Part D plans the discretion to furnish safe disposal information to the beneficiary during the CMR, a TMR, or another follow up service, depending upon the circumstances, as long as the required information is shared with each MTM program enrollee at least once per year. Specifically, we are proposing to revise § 423.153(d)(1)(vii) to include a requirement that all MTM enrollees receive at least annually, as part of the CMR, a TMR, or another follow up service, information about safe disposal of prescription drugs that are controlled substances, take back programs, in-home disposal, and cost-effective means of safe disposal that meets the criteria in § 422.111(j).

F. Automatic Escalation to External Review Under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries (§§ 423.153, 423.590, and 423.600)

CARA amended the Act to include new authority for Medicare Part D drug management programs effective on or after January 1, 2019. Final regulations were published in the April 2018 final rule (83 FR 16440) and provided at § 423.153(f), that a plan sponsor may establish a drug management program (DMP) for at-risk beneficiaries enrolled in their prescription drug benefit plans to address overutilization of frequently abused drugs. If an enrollee is identified as at-risk under a DMP, the individual has the right to appeal an at-risk determination under the rules in part 423, subparts M and U. In addition to the right to appeal an at-risk determination, an enrollee has the right to appeal the implementation of point-of-sale claim edits for frequently abused drugs that are specific to an at-risk beneficiary or a limitation of access to coverage for frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers or dispensed to the beneficiary by one or more network pharmacies (lock-in).

In the April 2018 final rule, we explained that the Secretary had discretion under the statute to provide

for automatic escalation of drug management program appeals to external review. We declined to exercise that discretion based on comments we received that cited to administrative efficiencies in using the existing Part D appeal process that is familiar to enrollees and plans. Accordingly, we implemented a final rule that follows the existing Part D benefit appeals process. Under existing Part D benefit appeals procedures, there is no automatic escalation to external review for adverse appeal decisions; instead, the enrollee (or prescriber, on behalf of the enrollee) must request review by the Part D IRE. Under the existing process, cases are auto-forwarded to the IRE only when the plan fails to issue a coverage determination within the applicable timeframe.

Subsequently, section 2007 of the SUPPORT Act amended section 1860D–4(c)(5) of the Act to require that, if on reconsideration a Part D sponsor affirms its denial of a DMP appeal, in whole or in part, the case shall be automatically forwarded to the independent outside entity contracted with the Secretary for review and resolution. We are proposing rules to codify that provision. For consistency with existing appeals regulations at part 422, subparts M and U, and for purposes of this proposal, the independent outside entity contracted with the Secretary is referred to as the Part D independent review entity (IRE) that is contracted with CMS to perform reconsiderations under the Part D program.

To implement the changes required by the SUPPORT Act, we are proposing revisions to the requirements for the content of the initial notice at § 423.153(f)(5)(ii)(C)(*3*) and the requirements for the second notice at § 423.153(f)(6)(ii)(C)(*4*)(*iii*). Specifically, we are proposing that these notices explain that if on redetermination a plan sponsor affirms its at-risk decision, in whole or in part, the enrollee's case shall be automatically forwarded to the IRE for review and resolution. While section 2007 of the SUPPORT Act refers to a plan sponsor affirming its denial, in whole or in part, on ''reconsideration,'' we are proposing revisions that reference a plan sponsor's ''redetermination,'' which is the term used throughout part 423, subparts M and U to describe the plan level appeal. We believe that use of the term ''redetermination'' is consistent with the intent of the SUPPORT Act that adverse plan level appeals be automatically forwarded to the IRE so that the IRE can review and resolve outstanding issues related to the individual's at-risk status under the plan sponsor's DMP.

We are also proposing to revise the requirements related to adjudication timeframes and responsibilities for making redeterminations at § 423.590 by adding paragraph (i) to state that if on redetermination the plan sponsor affirms, in whole or in part, its decision related to an at-risk determination under a DMP in accordance with § 423.153(f), the plan sponsor must forward the case to the IRE by the expiration of the applicable adjudication timeframe under paragraph (a)(2), (b)(2), or (d)(1) of § 423.590. We believe that requiring plan sponsors to automatically forward these cases within existing adjudication timeframes will promote timely review and resolution of issues remaining in dispute in accordance with the SUPPORT Act.

We are also proposing to revise § 423.600(b) to clarify that the requirement that the IRE solicit the views of the prescribing physician or other prescriber applies to determinations that are auto-forwarded to the IRE. Under this proposal, the Part D IRE would be required to accept and process cases where the plan sponsor has affirmed its denial on redetermination of an issue related to at-risk determinations made under § 423.153(f). In addition to the proposed change at § 423.600(b) as previously described, necessary modifications would be made to the Part D IRE's contract upon finalization of rules to implement section 2007 of the SUPPORT Act.

We believe these proposed changes related to auto-forwarding of adverse plan level appeals involving at-risk determinations made under plan sponsor DMPs afford the intended protections to individuals identified as at-risk and are consistent with the provisions of the SUPPORT Act. We welcome feedback on these proposals.

G. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

1. Medicare Parts C and D Fraud Efforts

CMS's role in overseeing the Medicare program is to ensure that payments are made correctly and that fraud, waste, and abuse are prevented and detected. Failure to do so endangers the Trust Funds and can even result in harm to beneficiaries. CMS has established various regulations over the years to address potentially fraudulent and abusive behavior in Medicare Parts C and D. For instance, 42 CFR 424.535(a)(14)(i) addresses improper prescribing practices and permits CMS to revoke a physician's or other eligible professional's enrollment if he or she has a pattern or practice of prescribing Part D drugs that is abusive or represents a threat to the health and safety of Medicare beneficiaries or both.

2. SUPPORT Act—Sections 2008 and 6063

a. Background

Opioid use disorder (OUD) and deaths from prescription and illegal opioid overdoses have reached alarming levels. The CDC estimated 47,000 overdose deaths were from opioids in 2017, and 36 percent of those deaths involved prescription opioids.[37] On October 26, 2017, Acting Health and Human Services Secretary, Eric D. Hargan, declared a nationwide public health emergency on the opioid crisis as requested by President Donald Trump.[38] This public health emergency has since been renewed several times by Secretary Alex M. Azar II.[39]

Section 2008 of the SUPPORT Act amends and adds several sections of the Act to address the concept of a ''credible allegation of fraud.'' Specifically:

- Sections 2008(a) and (b) of the SUPPORT Act amended sections 1860D–12(b) and 1857(f)(3) of the Act, respectively, by adding new requirements for Medicare Part D plan sponsors and MA organizations offering MA–PD plans. Specifically, the provisions—

++ Apply certain parts of section 1862(o) of the Act, regarding payment suspensions based on credible allegations of fraud, to Medicare Part D plan sponsors and MA organizations offering MA–PD plans, allowing them to impose payment suspensions on pharmacies in the same manner as these provisions apply to CMS;

++ Require these Part D plan sponsors and MA organizations offering MA–PD plans to notify the Secretary regarding the imposition of a payment suspension on a pharmacy pending an investigation of a credible allegation of fraud and does not extend the requirement to report to the Secretary other payment suspensions for which plan sponsors already have authority.

++ Require this notification to be made such as via a secure internet website portal (or other successor technology) established under section 1859(i).

[37] *https://www.cdc.gov/drugoverdose/data/index.html.*

[38] *https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.*

[39] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-19apr2019.aspx.*

• Section 2008(d) of the SUPPORT Act, which amended section 1862(o) of the Act, states that a fraud hotline tip (as defined by the Secretary) without further evidence shall not be treated as sufficient evidence for a credible allegation of fraud.

The effective date for these provisions of section 2008 of the SUPPORT Act is for plan years beginning on or after January 1, 2020.

Section 6063(a) of the SUPPORT Act, which added a new paragraph (i)(1) to section 1859 of the Act, requires the following:

• The Secretary, after consultation with stakeholders, shall establish a secure web-based program integrity portal (or other successor technology) that would allow secure communication among the Secretary, MA plans, and prescription drug plans, as well as eligible entities with a contract under section 1893, such as Medicare program integrity contractors. The purpose is to enable, through the portal:

++ The referral by such plans of substantiated or suspicious activities (as defined by the Secretary) of a provider of services (including a prescriber) or supplier related to fraud, waste, or abuse for the purpose of initiating or assisting investigations conducted by the eligible entity; and

++ Data sharing among such MA plans, prescription drug plans, and the Secretary.

• The Secretary shall disseminate the following information to MA plans and prescription drug plans via the portal: (1) Providers and suppliers referred for substantiated or suspicious activities during the previous 12-month period; (2) providers and suppliers who are currently either excluded under section 1128 of the Act or subject to a payment suspension pursuant to section 1862(o) or otherwise; (3) providers and suppliers who are revoked from Medicare, and (4) in the case the plan makes a referral via the portal concerning substantiated or suspicious activities of fraud, waste, or abuse of a provider or supplier, the Secretary shall notify the plan if the related providers or suppliers were subject to administrative action under title XI or XVIII for similar activities.

• The Secretary shall, through rulemaking, specify what constitutes substantiated or suspicious activities of fraud, waste, or abuse, using guidance such as that provided in the CMS Pub. 100–08, Medicare Program Integrity Manual (PIM), chapter 4, section 4.8. In section 4.8 of the PIM, CMS provides guidance to its Medicare program integrity contractors on the disposition of cases referred to law enforcement. Similar to what is stated in section 2008(d) of the SUPPORT Act, a fraud hotline tip without further evidence does not constitute sufficient evidence for substantiated fraud, waste, or abuse.

• On at least a quarterly basis, the Secretary must make available to the plans information on fraud, waste, and abuse schemes and trends in identifying suspicious activity. The reports must include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders. This information must be anonymized data submitted by plans without identifying the source of such information.

The effective date for these provisions of section 6063(a) of the SUPPORT Act is beginning not later than 2 years after the date of enactment, or by October 24, 2020.

Furthermore, section 6063(b) of the SUPPORT Act, which amended section 1857(e) of the Act, requires MA organizations and Part D plan sponsors to submit to the Secretary, information on investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier related to fraud, and other actions taken by such plans, related to inappropriate prescribing of opioids. The Secretary shall, in consultation with stakeholders, establish a process under which MA organizations and Part D plan sponsors must submit this information. In addition the Secretary shall establish a definition of inappropriate prescribing, which will reflect the reporting of investigations and other corrective actions taken by MA organizations and Part D plan sponsors to address inappropriate prescribing of opioids and the types of information that must be submitted.

The effective date for these provisions of section 6063(b) of the SUPPORT Act is for plan years beginning on or after January 1, 2021.

b. Need for Additional Measures

Existing regulations for MA and Part D plan sponsors in §§ 422.503(b)(4)(vi)(G)(*3*) and 423.504(b)(4)(vi)(G)(*3*) specify that plan sponsors should have procedures to voluntarily self-report potential fraud or misconduct related to the MA and Part D programs to CMS or its designee. (We note that § 422.503(b) generally outlines requirements that MA organizations must meet. Section 423.504(b) outlines conditions necessary to contract as a Part D plan sponsor.) Presently, MA organizations and Part D plan sponsors voluntarily report such data to CMS through either—(1) direct submissions to CMS, or (2) communication with the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC). Given the gravity of the nationwide opioid epidemic and the need for CMS and the plans to have as much information about potential and actual prescribing misbehavior as possible in order to halt such misbehavior, we believe that further regulatory action in this regard is warranted. Sections 2008 and 6063 of the SUPPORT Act provide the authority to establish regulations to implement a requirement for plans to report certain related data.

3. Proposed Provisions

Consistent with the foregoing discussion, we propose the following regulatory provisions to implement sections 2008 and 6063 of the SUPPORT Act. As explained, some of our proposals would modify or supplement existing regulations, while others would establish new regulatory paragraphs altogether. Existing (and our proposed) regulations related to Part C/MA are addressed in 42 CFR part 422; those pertaining to Part D are addressed in 42 CFR part 423. Regulations pertaining to or contained in other areas of title 42 will be noted as such.

a. Definitions

The definitions outlined below will be effective following the required statutory deadlines for each reporting piece described in the SUPPORT Act. Therefore, substantiated or suspicious activities of fraud, waste or abuse and fraud hotline time would be effective beginning October 24, 2020. Inappropriate prescribing of opioids and credible allegations of fraud would be effective beginning January 1, 2021.

(1) Substantiated or Suspicious Activities of Fraud, Waste, or Abuse

We indicated earlier that section 6063(a) of the SUPPORT Act added a new section 1859(i)(1) to the Act requiring the establishment of a regulatory definition of ''substantiated or suspicious activities of fraud, waste, or abuse,'' using guidance such as that in CMS Pub. 100–08, PIM, chapter 4, section. 4.8. To this end, we propose to add to §§ 422.500 and 423.4 a definition specifying that substantiated or suspicious activities of fraud, waste or abuse means and includes, but is not limited to allegations that a provider of services (including a prescriber) or supplier: Engaged in a pattern of improper billing; submitted improper claims with suspected knowledge of their falsity; submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or is

the subject of a fraud hotline tip verified by further evidence.

Consistent with the reference in section 6063(a) of the SUPPORT Act to chapter 4 of the PIM, our proposed definition largely mirrors that in section 4.8 of the PIM. We also believe that this definition is, importantly, broad enough to capture a wide variety of activities that could threaten Medicare beneficiaries and the Trust Funds. We solicit public comment on this definition.

(2) Inappropriate Prescribing of Opioids

Section 6063(b) of the SUPPORT Act, as mentioned previously, states the Secretary is required to establish: (1) A definition of inappropriate prescribing; and (2) a method for determining if a provider of services meets that definition. MA organizations and Part D Plan Sponsors must report actions they take related to inappropriate prescribing of opioids. We accordingly propose to add the following definition of inappropriate prescribing with respect to opioids. We propose to add this definition to §§ 422.500 and 423.4. We propose that inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by MA organizations and Part D Plan Sponsors, there is an established pattern of potential fraud, waste and abuse related to prescribing of opioids, as reported by the Plan Sponsors. Plan Sponsors may consider any number of factors including, but not limited to the following: Documentation of a patient's medical condition; identified instances of patient harm or death; medical records, including claims (if available); concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm; levels of Morphine Milligram Equivalent (MME) dosages prescribed; absent clinical indication or documentation in the care management plan, or in a manner that may indicate diversion; State level prescription drug monitoring program (PDMP) data; geography, time and distance between a prescriber and the patient; refill frequency and factors associated with increased risk of opioid overdose.

We believe the many steps that CMS, the CDC, and HHS have taken in response to the nation's opioid crisis have had an overall positive impact on clinician prescribing patterns, resulting in safer and more conscientious opioid prescribing across clinician types and across the settings where beneficiaries receive treatment for pain, and have also resulted in heightened public awareness of the risks associated with opioid medications. Recent HHS guidance [40] for example, highlights the importance of judicious opioid prescribing that minimizes risk and; urges collaborative, measured approaches to opioid dose escalation, dose reduction, and discontinuation; furthermore, a 2019 HHS Task Force report [41] outlines best practices for multimodal approaches to pain care. In this definition, we recognize that there are legitimate clinical scenarios that may necessitate a higher level of opioid prescribing based on the clinician's professional judgement, including, the beneficiary's clinical indications and characteristics, whether the prescription is for an initial versus a subsequent dose, clinical setting in which the beneficiary is being treated, and various other factors. We welcome public comments on specific populations or diagnoses that could be excluded for purposes of this definition, such as cancer, hospice, and/or sickle cell patients. Based upon widely accepted principles of statistical analysis and taking into account clinical considerations mentioned previously, CMS may consider certain statistical deviations to be instances of inappropriate prescribing of opioids. We also welcome evidence from clinical experts regarding evidence based guidelines for opioid prescribing across clinical specialties and care settings that could be considered to develop meaningful and appropriate outlier methodologies. Therefore, we propose that inappropriate prescribing of opioids should be based on an established pattern as previously described in this section utilizing many parameters.

We solicit public comment on other reasonable measures of inappropriate prescribing of opioids.

(3) Credible Allegation of Fraud

Somewhat similar to section 6063(a) of the SUPPORT Act, section 2008(d) of the SUPPORT Act states that a fraud hotline tip (as defined by the Secretary) without further evidence shall not be treated as sufficient evidence for a credible allegation of fraud. The term ''credible allegation of fraud'' is currently defined at §§ 405.370 and 455.2 (which, respectively, apply to Medicare and Medicaid) as an allegation from any source including, but not limited to the following: (1) Fraud hotline complaints; (2) claims data mining; and (3) patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability, and, in the case of § 455.2, the State Medicaid agency has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis.

To address this section 2008(d) of the SUPPORT Act requirement, we propose to revise the term ''credible allegation of fraud'' in §§ 405.370 and 455.2 as follows. We propose that the existing version of paragraph (1) in both §§ 405.370 and 455.2 would be amended to state ''Fraud hotline tips verified by further evidence.'' The existing version of paragraph (2) and (3) would remain unchanged. Similarly, we propose to add in § 423.4 a definition of credible allegation of fraud stating that a credible allegation of fraud is an allegation from any source including, but not limited to: Fraud hotline tips verified by further evidence; claims data mining; patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability. In the case of § 423.4, examples of claims data mining would include, but are not limited to, prescription drug events and encounter data mining. We solicit public comment on this definition.

(4) Fraud Hotline Tip

Sections 2008(d) and 6063(a) of the SUPPORT Act require the Secretary to define a fraud hotline tip. To this end, we propose to add to §§ 405.370, 422.500, 423.4, and 455.2 a plain language definition of this term. We propose that a fraud hotline tip would be defined as a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for that purpose, such as the federal government's HHS Office of the Inspector General (OIG) Hotline or a health plan's fraud hotline. This definition is intended to be broad enough to describe mechanisms such as the federal government's HHS OIG Hotline or a commercial health plan's fraud hotline. Many private plans, which have their own fraud reporting hotlines, participate as plan sponsors in Medicare Part D and this definition would seek to reflect their processes for reporting information on potential fraud, waste and abuse. We solicit public comment on this definition.

[40] ''HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics'' found at *https://www.hhs.gov/opioids/sites/default/files/2019-10/8-Page%20version__HHS%20Guidance%20for%20Dosage%20Reduction%20or%20Discontinuation%20of%20Opioids.pdf.*

[41] *https://www.hhs.gov/ash/advisory-committees/pain/index.html.*

b. Reporting

(1) Vehicle for Reporting

We plan to utilize a module within the HPMS as the program integrity portal for information collection and dissemination. The portal would serve as the core repository for the data addressed in sections 2008 and 6063 of the SUPPORT Act. Such data and the regular submission and dissemination of this important information would, in our view, strengthen CMS' ability to oversee plan sponsors' efforts to maintain an effective fraud, waste, and abuse program. We further believe that data sharing via use of a portal would, in conjunction with our proposals, help accomplish the following objectives in our efforts to alleviate the opioid epidemic:

- Enable CMS to perform data analysis to identify fraud schemes.
- Facilitate transparency among CMS and plan sponsors through the exchange of information.
- Provide better information and education to plan sponsors on potential fraud, waste, and abuse issues, thus enabling plan sponsors to investigate and take action based on such data.
- Improve fraud detection across the Medicare program, accordingly allowing for increased recovery of taxpayer funds and enrollee expenditures (for example, premiums, co-insurance, other plan cost sharing).
- Provide more effective support, including leads, to plan sponsors and law enforcement.
- Increase beneficiary safety through increased oversight measures.

(2) Type of Data To Be Reported by Plans

Sections 422.503(b)(4)(vi)(G)(*3*) and 423.504(b)(4)(vi)(G)(*3*), as noted, state that plan sponsors should have procedures to voluntarily self-report potential fraud or misconduct related to the MA and Part D programs, respectively, to CMS or its designee. To conform to the aforementioned requirements of sections 2008(a) and (b) and section 6063(b) of the SUPPORT Act, we propose to add new regulatory language, effective beginning in 2021, in parts 422 and 423 as stated throughout this section.

First, we propose new language at §§ 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*) to include the new provisions. We propose that the new §§ 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*) would state that the MA organization or Part D plan sponsor, respectively, must have procedures to identify, and must report to CMS or its designee either of the following, in the manner described in paragraphs (b)(4)(vi)(G)(*4*) through (*6*) of this section:

- Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o)(1) of the Act; and
- Any information related to the inappropriate prescribing of opioids and concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan. Second, we propose that new §§ 422.503(b)(4)(vi)(G)(*5*) and 423.504(b)(4)(vi)(G)(*5*) would require the data referenced in proposed §§ 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*) to be submitted via the program integrity portal. We propose that MA organizations and Part D plan sponsors would have to submit the data elements, specified below, in the portal when reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies; information related to the inappropriate prescribing of opioids and concerning investigations and credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by plan sponsors; or if the plan reports a referral, through the portal, of substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste or abuse to initiate or assist with investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners. The data elements, as applicable, are as follows:

- Date of Referral.
- Part C or Part D Issue.
- Complainant Name.
- Complainant Phone.
- Complainant Fax.
- Complainant Email.
- Complainant Organization Name.
- Complainant Address.
- Complainant City.
- Complainant State.
- Complainant Zip.
- Plan Name/Contract Number.
- Plan Tracking Number.
- Parent Organization.
- Pharmacy Benefit Manager.
- Beneficiary Name.
- Beneficiary Phone.
- Beneficiary Health Insurance Claim Number (HICN).
- Beneficiary Medicare Beneficiary Identifier (MBI).
- Beneficiary Address.
- Beneficiary City.
- Beneficiary State.
- Beneficiary Zip.
- Beneficiary Date of Birth (DOB).
- Beneficiary Primary language.
- Beneficiary requires Special Accommodations. If Yes, Describe.
- Beneficiary Medicare Plan Name.
- Beneficiary Member ID Number.
- Whether the Beneficiary is a Subject.
- Did the complainant contact the beneficiary? If Yes, is there a Report of the Contact?
- Subject Name.
- Subject Tax Identification Number (TIN).
- Does the Subject have Multiple TIN's? If Yes, provide.
- Subject NPI.
- Subject DEA Number.
- Subject Medicare Provider Number.
- Subject Business.
- Subject Phone Number.
- Subject Address.
- Subject City.
- Subject State.
- Subject Zip.
- Subject Business or Specialty Description.
- Secondary Subject Name.
- Secondary Subject Tax Identification Number (TIN).
- Does the Secondary Subject have Multiple TIN's? If Yes, provide.
- Secondary Subject NPI.
- Secondary Subject DEA Number.
- Secondary Subject Medicare Provider Number.
- Secondary Subject Business.
- Secondary Subject Phone Number.
- Secondary Subject Address.
- Secondary Subject City.
- Secondary Subject State.
- Secondary Subject Zip.
- Secondary Subject Business or Specialty Description.
- Complaint Prior MEDIC Case Number.
- Period of Review.
- Complaint Potential Medicare Exposure.
- Whether Medical Records are Available.
- Whether Medical Records were Reviewed.
- Whether the submission has been Referred to Law Enforcement. Submission Accepted? If so, provide Date Accepted.
- What Law Enforcement Agency(ies) has it been Referred to.
- Whether HPMS Analytics and Investigations Collaboration Environment for Fraud, Waste, and Abuse (AICE–FWA) was Used.
- Whether the submission has indicated Patient Harm or Potential Patient Harm.

• Whether the submission has been Referred. If so, provide Date Accepted.
• What Agency was it Referred to.
• Description of Allegations/Plan Sponsor Findings.

We note that the requirement for reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies under § 422.503(b)(4)(vi)(G)(*4*) would only apply to Medicare Part C in the context of Medicare Advantage Prescription Drug Plans (MA–PD plans). We believe this information is necessary to enable CMS to fully and completely understand the identity of the applicable party, the specific behavior involved, and the status of the action. We solicit public comment on these proposed requirements

(3) Timing of Plan Sponsor's Reporting

We propose in new §§ 422.503(b)(4)(vi)(G)(*6*)(*i*) and 423.504(b)(4)(vi)(G)(*6*)(*i*) that MA organizations and Part D plan sponsors would be required to notify the Secretary, or its designee of a payment suspension described in §§ 422.503(b)(4)(vi)(G)(*4*)(*i*) and 423.504(b)(4)(vi)(G)(*4*)(*i*) 14 days prior to implementation of the payment suspension. This timeframe will allow CMS to provide our law enforcement partners sufficient notice of a payment suspension to be implemented that may impact an ongoing investigation into the subject. We propose in the new §§ 422.503(b)(4)(vi)(G)(*6*)(*ii*) and 423.504(b)(4)(vi)(G)(*6*)(*ii*) that plans would be required to submit the information described in §§ 422.503(b)(4)(vi)(G)(*4*)(*ii*) and 423.504(b)(4)(vi)(G)(*4*)(*ii*) no later than January 15, April 15, July 15, and October 15 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. We propose that plans would be required to submit information beginning in 2021. For the first reporting period (January 15, 2021), the reporting will reflect the data gathered and analyzed for the previous quarter in the calendar year (October 1–December 31). We believe that quarterly updates would be frequent enough to ensure that the portal contains accurate and recent data while giving plans sufficient time to furnish said information. We solicit public comment on the proposed timing of reporting by plans.

(4) Requirements and Timing of CMS' Reports

As mentioned earlier in this proposed rule, section 6063(a) of the SUPPORT Act requires the Secretary make available to the plans, not less frequently than quarterly, information on fraud, waste, and abuse schemes and trends in identifying suspicious activity. The reports must include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders. Moreover, the information must be anonymized data submitted by plans without identifying the source of such information.

Section 6063 of the SUPPORT Act requires the Secretary provide reports no less frequently than quarterly. Consistent with this requirement, we propose in the new §§ 422.503(b)(4)(vi)(G)(*7*)(*i*) through (*iv*) and 423.504(b)(4)(vi)(G)(*7*)(*i*) through (*iv*) that CMS will provide MA organizations and Part D plan sponsors with data report(s) or links to data no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. We propose that CMS would provide this information beginning in 2021. For the first quarterly report (April 15, 2021), the report will reflect the data gathered and analyzed for the previous quarter submitted by the plan sponsors on January 15, 2021. Similar to the timing requirements related to new §§ 422.503(b)(4)(vi)(G)(*6*)(*ii*) and 423.504(b)(4)(vi)(G)(*6*)(*ii*), we believe that quarterly updates would strike a suitable balance between the need for frequently updated information while giving CMS time to review and analyze this data in preparation for complying with new §§ 422.503(b)(4)(vi)(G)(*4*) through (*7*) and 423.504(b)(4)(vi)(G)(*4*) through (*7*). We solicit public comment on the proposed timing of CMS dissemination of reports to plans.

IV. Implementation of Certain Provisions of the 21st Century Cures Act

A. Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

Section 4001 of the Balanced Budget Act of 1997 (hereinafter referred to as the BBA of 1997) added sections 1851 through 1859 to the Act establishing Part C of the Medicare program known originally as ''Medicare + Choice'' and later as ''Medicare Advantage (MA).'' As enacted, section 1851 of the Act provided that every individual entitled to Medicare Part A and enrolled under Part B, except for individuals with end stage renal disease (ESRD), could elect to receive benefits through an MA plan. The statute further permitted that, in the event that an individual developed ESRD while enrolled in an MA plan or in a health plan offered by the MA organization, he or she could remain in that MA plan or could elect to enroll in another health plan offered by that organization. These requirements were codified at § 422.50(a)(2) in the initial implementing regulations for the Part C program published in 1998 (63 FR 35071).

Section 1851 of the Act was subsequently amended several times to expand coverage of ESRD beneficiaries in MA plans.

• Section 620 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (hereinafter referred to as BIPA), established a one-time opportunity for individuals, medically determined to have ESRD, whose enrollment in an MA plan was terminated or discontinued after December 31, 1998, to enroll in another MA plan. The exception, codified in our regulations at § 422.50(a)(2)(ii) (68 FR 50855), was effective December 14, 2000, but was retroactive, to include individuals whose enrollment in an MA plan was terminated involuntarily on or after December 31, 1998.

• Section 231 of the MMA gave the Secretary authority to waive section 1851(a)(3)(B) of the Act, which precludes beneficiaries with ESRD from enrolling in MA plans. Under this authority, CMS undertook rulemaking to allow individuals with ESRD to join an MA special needs plan. This was codified at §§ 422.50(a)(2)(iii) and 422.52(c) (70 FR 4715) and was effective for the 2006 plan year.

In 2016, paragraph (a) of section 17006 of the Cures Act further amended section 1851 of the Act to remove the prohibition for beneficiaries with ESRD from enrolling in an MA plan. This change is effective for plan years beginning on or after January 1, 2021. (Please see sections IV.B. and IV.C. of this proposed rule for further changes established by section 17006 of the Cures Act.) To implement these changes in eligibility for MA plan enrollment made by the Cures Act, we propose the following amendments:

• Section 422.50(a)(2) would be revised to specify that the prohibition of beneficiaries with ESRD from enrolling in MA plans (and associated exemptions) is only applicable for coverage prior to January 1, 2021. Because of this limit on the prohibition

to plan years before 2021, the regulatory prohibition on enrollment in an MA plan by a beneficiary with ESRD will not apply to future periods. The exceptions to that prohibition would be similarly limited as the exceptions would no longer be necessary after January 1, 2021.

- Section 422.52(c) would be revised to specify that CMS authority to waive the enrollment prohibition in § 422.50(a)(2) to permit ESRD beneficiaries to enroll in a special needs plan would also only be applicable for plan years prior to 2021. Because there will be no additional limitations on enrollment by beneficiaries with ESRD beginning 2021, this waiver authority is unnecessary for that period.
- Section 422.110(b) would be revised to specify that the exception to the anti-discrimination requirement, which was adopted to account for the prohibition on MA enrollment by beneficiaries who have ESRD, is only applicable for plan years prior to 2021.

We considered whether § 422.66(d)(1), which requires MA organizations to accept enrollment in their MA plans by newly eligible Medicare beneficiaries who are seamlessly converting from health plan coverage offered by the MA organization and who are otherwise eligible for the MA plan, would also need to be amended to implement the eligibility changes made by the Cures Act. Section 422.66(d)(1) already provides that this right to seamlessly convert to an MA plan in the circumstances outlined in the regulation applies regardless whether the individual has ESRD. Therefore, we do not believe that any amendment to the regulation is necessary to ensure that the Cures Act change in MA eligibility is implemented. We solicit comment on this issue.

As noted previously in this rule, the changes mandated by the Cures Act do not take effect until the 2021 plan year. As such, individuals entitled to Medicare Part A and enrolled under Part B, and medically determined to have ESRD, are not eligible to choose to receive their coverage and benefits through an MA plan prior to plan year 2021, subject to the limited exceptions reflected in the current regulation text.

B. Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries (§ 422.322)

The MA organization is generally responsible for furnishing or providing coverage of all Medicare Part A and Part B benefits, excluding hospice, for its enrollees. The Medicare FFS program does not pay health care providers for furnishing these benefits to such enrollees. Section 1851(i) of the Act generally provides that, subject to specific exceptions, CMS pays only the MA organization for the provision of Medicare-covered benefits to a Medicare beneficiary who has elected to enroll in an MA plan. There are specific, statutory exceptions to this general rule in the statute, such as authority in section 1853(h) of the Act for FFS Medicare payment for Medicare-covered hospice services that an MA plan is prohibited by statute from covering. Section 17006(c) of the Cures Act amended section 1852(a)(1)(B)(i) of the Act to exclude from the list of items or services an MA plan is required to cover for an MA enrollee coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d) of the Act. Effective January 1, 2021, these costs will be covered under the original Medicare FFS program, pursuant to an amendment by section 17006(c)(2) of the Cures Act to section 1851(i) of the Act. As amended, section 1851(i)(3) of the Act authorizes FFS Medicare payment for the expenses for organ acquisitions for kidney transplants described in section 1852(a)(1)(B)(i) of the Act. We are proposing conforming regulatory changes to reflect the revision to the statute.

Specifically, we propose to revise § 422.322, which describes the source of payment and effect of MA plan election on payment for Medicare-covered benefits. Paragraphs (b) and (c) of § 422.322 generally track the statutory requirements that, subject to specific exceptions, CMS payment to MA organizations is in lieu of the amounts that would otherwise be payable under the original Medicare FFS program for Medicare-covered benefits furnished to an MA enrollee and are the only payment by the government for those Medicare-covered services. Consistent with the amendments to sections 1851(i) and 1852(a)(1)(B)(i) of the Act, we are proposing to amend § 422.322 to add a new paragraph (d) to reflect that expenses for organ acquisitions for kidney transplants are an exception to the terms outlined in paragraphs (b) and (c), and will be covered by original Medicare. Our proposed new paragraph (d) generally tracks how section 17006(c) of the Cures Act amends section 1851(i)(3) of the Act.

The Cures Act does not provide for Medicare FFS coverage of organ acquisition costs for kidney transplants incurred by PACE participants. Therefore, PACE organizations must continue to cover organ acquisition costs for kidney transplants, consistent with the requirement described in section 1894(b)(1)(A)(i) of the Act that PACE organizations provide all Medicare-covered items and services. Accordingly, CMS will continue to include the costs for kidney acquisitions in PACE payment rates.

C. Exclusion of Kidney Acquisition Costs From Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306)

Section 17006(b) of the Cures Act amended section 1853 of the Act to require that the Secretary's estimate of standardized costs for payments for organ acquisitions for kidney transplants be excluded from Medicare Advantage (MA) benchmarks and capitation rates, effective January 1, 2021. As amended, section 1853(k)(5) of the Act provides for the exclusion from the applicable amount and section 1853(n)(2) provides for the exclusion from the specified amount of the Secretary's estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under the Medicare statute (including expenses covered under section 1881(d) of the Act). As discussed in greater detail in the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes Final Rule (hereinafter referred to as the April 2011 final rule) (76 FR 21431, 21484 through 21485) and the annual Advance Notices and Rate Announcements starting with Payment Year 2012,[42] the applicable amount and the specified amount are used in the calculation of the MA benchmarks and capitation rates. We are proposing to revise the relevant regulations to reflect these amendments.

Specifically, we propose to revise § 422.258, which describes the calculation of MA benchmarks. Under section 1853(n)(1)(B) of the Act and § 422.258(d) of the regulations, for 2012 and subsequent years, the MA benchmark for a payment area for a year is equal to the amount specified in section 1853(n)(2) of the Act (that is, the ''specified amount''), but cannot exceed the applicable amount as described in 1853(n)(4) and § 422.258(d)(2). Prior to enactment of the Cures Act, section 1853(n)(2)(A) of the Act described the specified amount as the product of the base payment amount for an area for a year (adjusted to take into account the

[42] The Advance Notice and Rate Announcement for each year are available online at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.*

phase-out in the indirect costs of medical education from capitation rates) and the applicable percentage for the area and year. The base payment amount is, for years after 2012, the average FFS expenditure amount specified in § 422.306(b)(2). Section 17006(b)(2)(A) of the Cures Act amended section 1853(n)(2)(A)(i) of the Act to require that, for 2021 and subsequent years, the base payment amount used to calculate the specified amount must also be adjusted to take into account the exclusion of payments for organ acquisitions for kidney transplants from the capitation rate. We are proposing to make conforming amendments to paragraphs (d)(3), (5), and (6) of § 422.258. As amended, paragraph (d)(3) will specify that for 2021 and subsequent years, the base payment amount used to calculate the specified amount is required to be adjusted to take into account the exclusion of payments for organ acquisitions for kidney transplants. Also, as amended, paragraphs (d)(5) and (6) will specify that the average FFS expenditure amount used to determine the applicable percentage is adjusted to take into account the exclusion of payments for organ acquisitions for kidney transplants. To make these amendments, we propose to insert references to the adjustment made under § 422.306(d) to modify the various references to the base payment amount in paragraphs (d)(3) and (5), (d)(5)(i) and (ii), and (d)(6).

We also propose to amend § 422.306 by revising the introductory text and adding a new paragraph (d). Proposed paragraph (d) would describe the required adjustment, beginning for 2021, to exclude the Secretary's estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under this title (including expenses covered under section 1881(d) of the Act) in the area for the year. By operation of § 422.258(d)(2), the applicable amount is established by reference to § 422.306, and the rules there for calculation of MA annual capitation rates. By adding § 422.306(d), we would implement the new language in section 1853(k)(5) of the Act (added by section 17006(b)(1)(B) of the Cures Act) to require the adjustment to exclude payments for organ acquisitions for kidney transplants. We request comment whether these proposed revisions to §§ 422.258(d) and 422.306 adequately implement the statutory changes made by section 17006 of the Cures Act to require exclusion of the costs of kidney acquisition from the applicable amount and the specified amount for purposes of setting MA benchmarks and capitation rates.

Per section 1853(a)(1)(H) of the Act, CMS is required to establish separate rates of payment to an MA organization for individuals with end stage renal disease (ESRD) who are enrolled in a plan offered by that organization. This special rule for ESRD payment rates is codified in the regulations at 42 CFR 422.304(c). Since the Cures Act requires FFS Medicare payment for kidney acquisition costs for all MA enrollees, including MA enrollees with ESRD, we propose to apply the exclusion of kidney acquisition costs to the ESRD payment rates. As § 422.304(c) does not prescribe the specific methodology CMS must use to determine the separate rates of payment for ESRD enrollees described in section 1853(a)(1)(H) of the Act, the exclusion of kidney acquisition costs from ESRD rates does not require regulatory amendment. CMS will address the methodology for excluding kidney acquisition costs from MA benchmarks (including the MA ESRD state rates) in the 2021 Advance Notice and Rate Announcement. Section 1894(d)(2) of the Act requires that PACE capitation amounts be based upon MA payment rates established under section 1853 of the Act and adjusted to take into account the comparative frailty of PACE enrollees and such other factors as the Secretary determines to be appropriate. While capitated payments made to PACE organizations are based on the applicable amount under section 1853(k)(1) of the Act, CMS will include the costs for kidney acquisitions in PACE rates. Because PACE organizations are required to cover all Medicare-covered items and services under section 1894(b)(1)(A)(i) of the Act, including organ acquisition costs for kidney transplants, CMS will include kidney acquisition costs in PACE payment rates, including PACE ESRD rates. This approach is consistent with how PACE organizations have historically been paid for kidney acquisition costs for PACE enrollees.

V. Enhancements to the Part C and D Programs

A. Reinsurance Exceptions (§ 422.3)

Section 1855(b) of the Act requires MA organizations to assume full financial risk on a prospective basis for the provision of basic benefits (and, for plan years before 2006, additional benefits required under section 1854 of the Act) furnished to MA plan enrollees, subject to the exceptions listed in the statute at section 1855(b)(1)–(4) of the Act. The exception at section 1855(b)(1) of the Act states that an MA organization may obtain insurance or make arrangements for the cost of providing to any enrolled member such services the aggregate value of which exceeds a per-enrollee aggregate level established by the Secretary. Section 1855(b)(1) of the Act describes stop loss insurance arrangements but we are not using those terms in the regulation in order to be specific in describing the form of the arrangement. Section 1855(b)(1) of the Act permits an MA organization to obtain insurance or make other arrangements under which the MA organization bears less than full financial risk for the costs of providing basic benefits for an individual enrollee that exceed a certain threshold. For the reasons discussed in this section of this proposed rule, we are proposing to implement, at a new § 422.3, the exception at section 1855(b)(1) of the Act and establish in regulation options to use insurance for costs beyond a specified threshold. We are proposing that an MA organization may obtain insurance (that is, reinsurance) or make other arrangements for the cost of providing basic benefits to an individual enrollee the aggregate value of which exceeds $10,000 during a contract year or, alternatively, such costs may be shared proportionately on a first dollar basis, the value of which is calculated on an actuarially equivalent basis to the cost of the insurance for costs that exceed $10,000 in a contract year. We also propose that if the MA organization chooses to purchase pro rata coverage that provides first dollar coverage, the price of that coverage cannot exceed the cost of the option of purchasing stop loss insurance for enrollee health care costs that exceed a threshold of $10,000 in a contract year. The statutory exceptions at section 1855(b)(2)–(4) of the Act still apply. This proposal serves to establish in regulation the threshold described in section 1855(b)(1) of the Act.

Because we interpret section 1855(b) of the Act as requiring an MA organization to remain at full financial risk for basic benefits, subject to the exceptions listed in subsections (b)(1) through (b)(4), we are proposing that the limits in proposed § 422.3 apply for purposes of insuring (or making other arrangements) for costs of providing basic benefits and therefore do not apply to supplemental benefits offered by MA organizations. We are implementing the exception at section 1855(b)((1) of the Act because concerns were raised that absent the implementation of specific standards by CMS under section 1855(b)(1) of the Act

there was ambiguity about the legal basis of MA organizations sharing risk through reinsurance. A number of MA organizations expressed concern to CMS about this legal uncertainty as they have utilized reinsurance within the MA program. Therefore, we are proposing to implement section 1855(b)(1) of the Act to formally establish reinsurance standards for the MA program and remove any uncertainty on the permitted utilization of reinsurance.

Under this proposed implementation of the exception at section 1855(b)(1) of the Act, MA organizations which are voluntarily choosing to purchase insurance to limit their exposure to enrollee medical losses will have two options. In the first option, an MA organization could purchase insurance that would stop losses for the MA organization for individual plan enrollees when an individual enrollee's covered costs for basic benefits exceed $10,000 during a contract year. Stated another way, the MA organization could have insurance for costs that exceed $10,000 for covering or furnishing basic benefits to an individual plan enrollee in the contract year. In the second option, an MA organization could purchase pro rata insurance coverage that would provide first dollar coverage provided that the value of the insured risk is actuarially equivalent to costs that exceed $10,000 and the insurance coverage is priced at an actuarial value not to exceed the cost of purchasing the stop loss insurance for medical expenses exceeding $10,000 per member per year. Specifically, the cost to the MA organization in purchasing first dollar pro rata insurance cannot exceed the cost to the MA organization of purchasing $10,000 per member per year stop loss insurance.

Based on discussions with the National Association of Insurance Commissioners (NAIC) and previous 2018 Call Letter comments we have received, CMS recognizes that the use of insurance by health care insurers is a common and long standing market practice for both commercial health insurers and MA organizations and that the practice serves to reduce financial exposure to changes in health care costs, helps manage capital requirements, and allows health care insurers to grow enrollment. Based on our discussions with the NAIC and earlier discussion with the industry it is our understanding that MA organizations located in areas with fewer beneficiary choices (for example, rural, underserved areas) may particularly benefit from using reinsurance because of how it provides financial stability for the MA organization, which in turn can lead to enhanced competition and consumer choice, especially in small and mid-sized market areas. Insuring part of the risk assumed under an MA plan is important for smaller MA organizations to compete with larger organizations that can independently finance their operations. We recognize that some may see hazards in excessive reinsurance to the extent that the direct health insurer (here, the MA organization) might pass a large share of their risk and premium through insurance and that the MA organization could be viewed as no longer possessing the primary responsibility for furnishing the health care services. While the statute identifies the category of risk for which an MA organization may seek insurance or other arrangements (such as, in section 1855(b)(1) of the Act, the cost of providing to any enrolled member such services the aggregate value of which exceeds an established threshold), it is in the context of a mandate that MA organizations assume full financial risk on a prospective basis for providing basic benefit to enrollees. Therefore, we are cognizant of the need to ensure that MA organizations are not transferring all the risk of providing services to enrollees to a third party that is not under contract with CMS. We seek to balance these different interests in setting the threshold for the individual stop loss insurance coverage authorized by the statute.

The $10,000 threshold we are proposing has its roots in our review of the Conference Report for the BBA of 1997 (H.R. Conf. Rep. 105–217) and the difference between the House bill and the Senate amendment on the threshold at which a Part C plan could reinsure per-enrollee costs. The Conference Report indicates that the House bill tracked existing language in section 1876(b)(2)(D)(i) of the Act in using a $5,000 per year threshold while the Senate amendment provided for an amount established by the agency with an annual adjustment using the Consumer Price Index-Urban (CPI–U) for the 12-month period ending with June of the previous year. The conference agreement was to adopt the language in section 1855(b)(1) of the Act that remains today: A threshold established by the agency from time to time. To develop the $10,000 threshold we are proposing, we started with the amount of $5,000 identified in the Conference Report and used the following methodology: We multiplied the amount identified in the Conference Report ($5,000) by the increase in the CPI–U. Our policy choice was heavily influenced by the description in the Conference Report of the Senate amendment: ''the applicable amount of insurance for 1998 is the amount established by the Secretary and for 1999 and any succeeding year, is the amount in effect for the previous year increased by the percentage change in the CPI-urban for the 12-month period ending with June of the previous year.'' In updating the threshold this way, we rounded the amount for each year to the nearest whole dollar. Actual CPI–U values through June 2019 were used to perform these calculations. After 2019, the CPI–U values are estimated using the Congressional Budget Office's August 2019 report: An Update to the Economic Outlook: 2019 to 2029.

Based on our scan of the market and current practices of commercial health insurers, in selecting the $10,000 threshold for stop loss insurance we believe the level of risk transfer we have proposed is reasonable and consistent with supporting robust competition in Medicare Advantage. We believe the proposed level of risk transfer is acceptable given that CMS closely monitors MA organizations in terms of their administration of their MA plans, and specifically their timely provision of medically necessary health care services to enrollees and their overall financial solvency. CMS has a direct contract with each MA organization and despite any insurance arrangements, the MA organization remains accountable to CMS for ensuring timely access for enrollees to medically necessary Medicare covered services. In addition, CMS through its regional offices, plan audits, review of enrollee appeals and stakeholder letters closely monitors the performance of MA organizations and intervenes whenever it has evidence an MA organization is not meeting its contractual obligations. Also, any insurance arrangement used by MA organizations is subject to state insurance regulation and oversight regarding solvency because section 1856(b)(3) of the Act does not preempt those laws or provide that CMS regulation supersedes them. It is also our understanding that the NAIC model laws (Model 785); NAIC Credit for Reinsurance Regulation (Model 786); and the NAIC Life and Health Reinsurance Agreements Model Regulation (Model 791) have been substantially adopted by all states. We believe CMS oversight along with the states' oversight of financial solvency substantially ensures that CMS will be able to intervene on a timely basis when an MA organization is experiencing solvency problems or is not meeting its obligation to appropriately furnish its

enrollees with benefits covered under the MA plan.

Notwithstanding our rationale for proposing this specific threshold, we recognize that the reinsurance marketplace is complex and evolving. Therefore, we solicit comments regarding our proposed reinsurance regulation generally and the specific threshold proposed; we are particularly interested in comments whether the $10,000 threshold is a reasonable level and if the flexibility we are proposing for MA organizations in permitting insurance or other arrangements that are actuarially equivalent to a $10,000 threshold is sufficient to serve the goals outlined here. In addition, we welcome comments that provide additional information about insurance or other arrangements for addressing the risk of costs that exceed specific thresholds on an individual enrollee basis.

Additionally, CMS wishes to clarify what we consider to be an MA organization for purposes of this statute and is proposing to broaden our interpretation to include parent organizations. The result of that would be to evaluate compliance with section 1855(b) of the Act and proposed § 422.3 at the parent organization level, such that risk sharing or allocations of losses and costs among wholly-owned subsidiaries would not be evaluated. Therefore, we are seeking comment on whether CMS should consider a parent organization to be part of an MA organization for purposes of section 1855(b) of the Act or whether CMS should consider a parent organizations to be a separate entity from an MA organization.

B. Out-of-Network Telehealth at Plan Option

On April 16, 2019, CMS finalized requirements for MA plans offering additional telehealth benefits (ATBs).[43] Section 50323 of the BBA of 2018 created a new subsection (m) of section 1852 of the Act, authorizing MA plans to offer ATBs to enrollees starting in plan year 2020 and treat ATBs as basic benefits. In the April 2019 final rule, we finalized a new regulation at § 422.135 to implement that authority. As part of the parameters for the provision of ATBs, we finalized a requirement, at § 422.135(d), that MA plans furnishing ATBs only do so using contracted providers. The regulation specifically provides that benefits furnished by a non-contracted provider through electronic exchange may only be covered by an MA plan as a supplemental benefit.

We finalized the proposal at § 422.135(d) to require that all MA plan types, including preferred provider organizations (PPOs), use only contracted providers to provide MA additional telehealth benefits. In the April 2019 final rule, CMS adopted a policy that services furnished by non-contracted providers through electronic exchange are not MA ATBs. We explained that limiting service delivery of MA ATBs to contracted providers offers MA enrollees access to these covered services in a manner consistent with the statute because plans would have more control over how and when services are furnished. In the April 2019 final rule, we took the position that limiting MA ATBs to contracted providers will ensure additional oversight of providers' performance, thereby increasing plans' ability to provide these benefits. In response to commenters' recommendation that CMS allow PPOs to provide ATBs through contracted and non-contracted providers, we clarified that if a PPO furnishes MA ATBs consistent with the requirements at § 422.135, then the PPO plan requirement at § 422.4(a)(1)(v) (that the PPO must furnish all services both in-network and out-of-network) will not apply to the MA additional telehealth benefits and all other benefits covered by the PPO must be covered on both an in-network and out-of-network basis. In other words, a PPO plan is not required to furnish its MA additional telehealth benefits out-of-network, as is the case for all other plan-covered services. However, a PPO plan may cover—as a supplemental benefit—telehealth services that are furnished out-of-network.

Although we took the position that limiting MA ATBs to contracted providers will ensure additional oversight of providers' performance in the April 2019 final rule, CMS is also considering whether limiting MA ATBs to contracted providers may unnecessarily limit the ability of MA plans to furnish ATBs. If CMS revises § 422.135(d) to allow all plan types to offer ATBs through non-contracted providers, CMS would leverage existing oversight programs, which include monitoring beneficiary complaints, organization determinations, and appeals related to MA ATBs. CMS has regularly scheduled meetings with the Part C Independent Review Entity (IRE) contractor; during these meetings, CMS and the IRE contractor identify and evaluate systemic problems with coverage decisions that rise to the level of the IRE. We would continue to hold plans accountable for ensuring sufficient oversight of medically necessary Medicare covered items and services such as MA ATBs through CMS's oversight activities and believe that we have the means to do that through these monitoring and oversight policies.

The statute does not prohibit MA plans' use of non-contracted providers to deliver ATBs. Therefore, CMS is considering whether to revise § 422.135 to permit ATBs to be provided by non-contracted providers in cases where the non-contracted providers satisfy ATB requirements set forth in the April 2019 final rule. CMS believes requiring non-contracted and contracted providers to meet the same ATB requirements will ensure ATBs are delivered in a manner consistent with the statute and plans will have necessary control over how and when services are furnished. We solicit comment whether § 422.135(d) should be revised to allow all MA plan types, including PPOs, to offer ATBs through non-contracted providers and treat them as basic benefits under MA.

C. Supplemental Benefits, Including Reductions in Cost Sharing (§ 422.102)

In the Medicare Program; Establishment of the Medicare Advantage Program Final Rule, published in the **Federal Register** on January 28, 2005 (hereinafter referred to as the January 2005 final rule) (70 FR 4588, 4617), CMS established that an MA plan could reduce cost sharing below the actuarial value specified in section 1854(e)(4)(B) of the Act only as a mandatory supplemental benefit and codified that policy at § 422.102(a)(4). In order to clarify the scope of section 1854(e)(4)(A) of the Act, we are proposing to amend § 422.102(a)(4) and add new rules at § 422.102(a)(5) and (a)(6)(i) and (ii) to further clarify the different circumstances in which an MA plan may reduce cost sharing for covered items and services as a mandatory supplemental benefit and to specifically authorize certain flexibility in the mechanisms by which an MA plan may make reductions in cost sharing available.

Currently, reductions in cost sharing are an allowable supplemental benefit in Medicare Advantage (MA) and may include:

- Reductions in the cost-sharing for Parts A and B benefits compared to the actuarially equivalent package of Parts A and B benefits; and

[43] Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021. Retrieved at: *https://www.federalregister.gov/documents/2019/04/16/2019-06822/medicare-and-medicaid-programs-policy-and-technical-changes-to-the-medicare-advantage-medicare.*

• Reductions in cost-sharing for Part C supplemental benefits, for example provided for specific services for enrollees that meet specific medical criteria, such that similarly situated enrollees (that is, all enrollees who meet the identified criteria) are treated the same and enjoy the same access to these targeted benefits.

We propose to codify regulation text to clarify that reductions in cost sharing for (1) Part A and B benefits and (2) covered items and services that are not basic benefits are allowable supplemental benefits but may only be offered as mandatory supplemental benefits at § 422.102(a)(4) and (5). We propose to revise the current language at § 422.102(a)(4) by inserting the phrase ''for Part A and B benefits'' after the cite to section 1854(e)(4)(A) of the Act and to add a new paragraph (a)(5) to specify that reduced cost sharing may be applied to items and services that are not basic benefits; for both categories, the reduction of cost sharing may only be provided as a mandatory supplemental benefit.

MA plans currently have options in how they may choose to structure mandatory supplemental benefits that are in the form of cost sharing reductions. For example, MA organizations may offer, as a supplemental benefit, a reimbursement or a debit card to reduce cost sharing towards plan covered services or to provide coverage of 100 percent of the cost of covered items. For instance, enrollees may be given a debit card with a dollar amount that can be used towards cost sharing for plan covered services. MA plans may also decide to offer, as a supplemental benefit, a reduction in cost through a maximum allowance. An MA plan may establish a dollar amount of coverage that may be used to reduce cost sharing towards plan covered services and subject to a plan-established annual limit; enrollees can ''spend'' the allowance on cost sharing for whichever covered benefits the enrollee chooses. In both scenarios, MA plans are expected to administer the benefit in a manner that ensures the debit card and/or allowance can only be used towards plan-covered services. We are proposing new regulation text, at § 422.102(a)(6)(i) and (ii), to codify these flexibilities in how reductions in cost sharing are offered. These flexibilities are only for Part C supplemental benefits, as defined in proposed § 422.102(c) and discussed in section VI.F. Of this proposed rule. Therefore, cost sharing for Part D drugs is not included in these flexibilities.

As proposed, the flexibilities identified here are permitted only as a mandatory supplemental benefit which is why we are proposing to codify them in § 422.102(a). Further, this proposed flexibility is only for items and services that are identified in the MA plan's bid and marketing and communication materials as covered benefits, which is why the proposed regulation text uses the terms ''covered benefits'' and ''coverage of items and services.'' Thus, MA plans would not be able to offer use of a debit card for purchase of items or services that are not covered. This is consistent with current guidance in Chapter 4 of the Medicare Managed Care Manual under section 40.3 that allows debit cards to be used for plan-covered over-the-counter items under the conditions that the card is exclusively linked to the OTC covered items and has a dollar limit tied to the benefit maximum. We recognize that a debit card could be utilized as a reimbursement mechanism or as a means for the MA plan to make its payment for an item or service; in either case, the use of the card is tied to coverage of the benefit. Like all other coverage, the flexibilities proposed here are limited to the specific plan year; therefore, this authority to use debit cards or a basket of benefits up to a set value from which an enrollee can choose cannot be rolled over into subsequent years. We have proposed specific text in paragraph (a)(6) limiting these forms of supplemental benefits to the specific plan year to emphasize that rolling over benefits to the following plan year is not permitted.

For both benefit options, as previously described, MA plans have the flexibility to establish a maximum plan benefit coverage amount for supplemental benefits or a combined amount that includes multiple supplemental benefits, such as a combined maximum plan benefit coverage amount that applies to dental and vision benefits. Plans may not offer reimbursement, including use of a debit card to pay for supplemental benefits that are not covered by the plan. Reductions in cost sharing as a supplemental benefit are subject to an annual limit that the enrollee can ''spend'' on cost sharing for whichever covered benefits the enrollee chooses. Plans may use a receipt-based reimbursement system or provide the dollar amount on a debit card (linked to an appropriate merchant and item/service codes) so that the enrollee may pay the cost sharing at the point of service. This provision codifies already existing guidance and practices and therefore is not expected to have additional impact above current operating expenses. Additionally, this provision amends definitions and therefore does not impose any collection of information requirements.

D. Referral/Finder's Fees (§§ 422.2274 and 423.2274)

In the Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Final Rule, published in the **Federal Register** on May 23, 2014 (79 FR 29960), CMS codified rules in §§ 422.2274(h) and 423.2274(h) for MA organizations and Part D plans to pay agents and brokers for referrals of beneficiaries for enrollment, also known as finder's fees. In the proposed language, we are clarifying our longstanding intent that compensation is on a per-enrollment basis. Since referral fees are part of compensation, organizations may not pay independent agents more than regulatory limits. Because referral fees are already incorporated into compensation, limiting the amount of a referral fee has no impact on the statutory requirement of an agent enrolling a beneficiary in the plan that best meets their health care needs. With respect to captive and employed agents, who only sell for one organization, the referral fees also have no impact given the organization sets rates of pay, nor is there a statutory steerage impact.

Therefore, we propose to remove §§ 422.2274(h) and 423.2274(h). As currently codified at §§ 422.2274(b) and 423.2274(b), compensation for initial enrollments may not exceed the fair market value and compensation for renewal enrollments may not exceed 50 percent of the fair market value. Compensation is defined in the same current regulation, at paragraph (a), as all monetary or non-monetary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to, commissions, bonuses, gifts, prizes or awards, or referral or finder fees. By eliminating the individual referral fee limit, we are restructuring the regulation to only provide for referral fees within the scope of Fair Market Value (FMV). Our proposal clarifies that MA organizations and Part D plans have the ability to compensate agents for referrals provided the total dollar amount does not exceed FMV. We believe that the primary value for this proposed additional flexibility is in connection with independent agents, as we believe that for captive and employed agents, referral/finder fees do not play a factor in making sure the agent enrolls the beneficiary in the best plan, since captive and employed agents

only sell for one organization. We therefore propose to eliminate the current specific limit on finder or referral fees that is codified at paragraph (h). Currently, the definition of compensation already includes referral or finder fees, so the result of this specific proposal would be an overall limit on compensation for initial and renewal enrollments, which includes finder or referral fees. In section VI.H. of this proposed rule, we also propose additional changes for §§ 422.2274(g) and 423.2274(g) regarding agent and broker compensation for Part C and Part D enrollments. Under those proposals, the definition of compensation continues to include finder or referral fees, so the limits on compensation continue to include finder or referral fees. We solicit comment on whether removing the limit on referral/finder's fees would generate concerns such as those discussed in the 2010 Call Letter for MA organizations issued March 30, 2009, CMS's October 19, 2011, memo entitled ''Excessive Referral Fees for Enrollments,'' or the ''Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' final rule that codified referral/finder's fees limits in regulation.

E. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)

1. Introduction

In the April 2018 final rule, CMS codified at §§ 422.160, 422.162, 422.164, and 422.166 (83 FR 16725 through 83 FR 16731) and §§ 423.180, 423.182, 423.184, and 423.186 (83 FR 16743 through 83 FR 16749) the methodology for the Star Ratings system for the MA and Part D programs, respectively. This was part of the Administration's effort to increase transparency and give advance notice regarding enhancements to the Part C and D Star Ratings program. Under those regulations, CMS must propose through rulemaking any future changes to the methodology for calculating the ratings, addition of new measures, and substantive changes to the measures. Sections 422.164(e) and 423.184(e) provide authority and a mechanism for the removal of measures for specific reasons (low statistical reliability and when the clinical guidelines associated with the measure change such that the specifications are no longer believed to align with positive health outcomes). Generally, removal of a measure for other reasons would also occur through rulemaking. In the 2020 Call Letter, CMS announced the removal of the Adult Body Mass Index Assessment (Part C), Appeals Auto-Forward (Part D), and Appeals Upheld (Part D) measures due to low statistical reliability starting with the 2020 measurement year and associated 2022 Star Ratings following the rules codified at §§ 422.164(e) and 423.184(e). The collection of Part D Timeliness Monitoring Project (TMP) data was also stopped for the 2020 measurement year since it was used to validate the two Part D appeals measures. In the April 2019 final rule, CMS amended §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to update the methodology for calculating cut points for non-Consumer Assessment of Healthcare Providers and Systems (non-CAHPS) measures by adding mean resampling and guardrails, codify a policy to adjust Star Ratings for disasters, and finalize some measure updates.

At this time, we are proposing to further increase the stability of cut points by modifying the cut point methodology for non-CAHPS measures through direct removal of outliers. We are also proposing to increase the weight of patient experience/complaints and access measures, remove the Rheumatoid Arthritis Management (Part C) measure from the Star Ratings because the measure steward is retiring the measure from the HEDIS measurement set, implement substantive updates to the specifications of the Health Outcomes Survey (HOS) outcome measures, add two new Part C measures to the Star Ratings program, clarify the rules around consolidations when data are missing due to data integrity concerns, and add several technical clarifications. We are also proposing to codify additional existing rules for calculating MA Quality Bonus Payment (QBP) ratings. Unless otherwise stated, these changes would apply (that is, data would be collected and performance measured) for the 2021 measurement period and the 2023 Star Ratings.

2. Definitions (§ 422.252)

We propose to amend the definition at § 422.252 for new MA plans by clarifying how we apply the definition. We are proposing to modify the definition as follows: *New MA plan* means a plan that meets the following: (1) Is offered under a new MA contract; and (2) is offered under an MA contract that is held by a parent organization defined at § 422.2 that has not had an MA contract in the prior 3 years. For purposes of this definition, the parent organization is identified as of April of the calendar year before the payment year to which the final QBP rating applies, and contracts associated with that parent organization are also evaluated using contracts in existence as of April of the 3 calendar years before the payment year to which the final QBP rating applies. Under our current policy, we identify the parent organization for each MA contract in April of each year and then whether any MA contracts have been held by that parent organization in the immediately preceding 3 years to determine if the parent organization meets the 3 year standard. For example, if a parent organization is listed for an MA contract in April 2019, and that parent organization does not have any other MA contracts in April 2019, April 2018, or 2017, the plans under the MA contract would be considered new MA plans for 2020 QBP purposes.

3. Measure-Level Star Ratings (§§ 422.166(a), 423.186(a))

Over the past 2 years, we have codified and refined the methodology for calculating the Star Ratings from the performance scores for non-CAHPS measures. At §§ 422.166(a) and 423.186(a), we initially codified the historical methodology for calculating Star Ratings at the measure level in the April 2018 final rule. The methodology for non-CAHPS measures employs a hierarchical clustering algorithm to identify the gaps that exist within the distribution of the measure-specific scores to create groups (clusters) that are then used to identify the cut points. The Star Ratings categories are designed such that the scores in the same Star Ratings category are as similar as possible and the scores in different Star Ratings categories are as different as possible. The current methodology uses only data from the most recent Star Ratings year; therefore, the cut points are sensitive to changes in performance from 1 year to the next.

The primary goal of any cut point methodology is to disaggregate the distribution of scores into discrete categories or groups such that each grouping accurately reflects true performance. The current MA Star Ratings methodology converts measure-specific scores to measure-level Star Ratings so as to categorize the most similar scores within the same measure-level Star Rating while maximizing the differences across measure-level Star Ratings. We solicited comments in the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit

Programs, and the PACE Program Proposed Rule (hereinafter referred to as the November 2017 proposed rule) regarding the approach to convert non-CAHPS measure scores to measure-level Star Ratings (82 FR 56397 through 56399). We requested input on the desirable attributes of cut points and recommendations to achieve the suggested characteristics in the Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Benefit, Programs for All-inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 Proposed Rule (hereinafter referred to as the November 2018 proposed rule). In addition, we requested that commenters either suggest alternative cut point methodologies or provide feedback on several options detailed in the November 2018 proposed rule, such as setting the cut points by using a moving average, using the mean of the 2 or 3 most recent years of data, or restricting the size of the change in the cut points from 1 year to the next.

The commenters identified several desirable attributes for cut points that included stability, predictability, and attenuation of the influence of outliers; commenters also suggested restricting movement of cut points from 1 year to the next and recommended that CMS either pre-announce cut points before the plan preview period or pre-determine cut points before the start of the measurement period. In the April 2018 final rule (83 FR 16567), we expressed appreciation for our stakeholders' feedback and stated our intent to use it to guide the development of an enhanced methodology while maintaining the intent of the cut point methodology to accurately reflect true performance.

Using the feedback from the comments we received in response to the November 2018 proposed rule, we considered enhancements to the methodology that would increase the stability and predictability of the cut points and finalized in the April 2019 final rule two enhancements to the historical methodology. In the April 2019 final rule, we amended §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to add mean resampling of the current year's data to the current clustering algorithm to attenuate the effect of outliers; we also added measure-specific caps in both directions to provide guardrails so that the measure-threshold-specific cut points do not increase or decrease more than the cap from 1 year to the next. Some commenters to the November 2018 proposed rule believed mean resampling would not be sufficient to address outliers and expressed support for directly removing outliers before clustering. We did not finalize an approach for directly removing outliers in the April 2019 final rule since the public did not have an opportunity to comment on a specific approach.

As we stated in the April 2019 final rule in response to public comments on this topic, we evaluated two options to address direct removal of outliers—trimming and Tukey outer fence outlier deletion. Under trimming, all contracts with scores below the 1st percentile or above the 99th percentile are removed prior to clustering. Although trimming is a simple way to remove extreme values, it removes scores below the 1st percentile or above the 99th percentile regardless of whether the scores are true outliers. This means in cases when true outliers are between the 1st and 99th percentile, they would not be removed by trimming, and in cases when the distribution of scores is skewed, scores that are not true outliers would be trimmed.

Tukey outer fence outlier deletion is a standard statistical method. Tukey outer fence outliers are sometimes called Whisker outliers. Under this methodology, outliers are defined as measure scores below a certain point (first quartile $-$ 3.0 $\times$ (third quartile $-$ first quartile)) or above a certain point (third quartile + 3.0 $\times$ (third quartile $-$ first quartile)). The Tukey outer fence outlier deletion will remove all outliers based on the previous definition and will not remove any cases that are not identified as outliers. Values identified by Tukey outer fence outlier deletion would be removed prior to clustering. If Tukey outer fence outlier deletion and a 5 percent guardrail had been implemented for the 2018 Star Ratings, 2 percent of MA–PD contracts would have seen their Star Rating increase by half a star, 16 percent would have decreased by half a star, and one contract would have decreased by 1 star. For PDP contracts, 2 percent would have increased by half a star, and 18 percent would have decreased by half a star. This simulation of the impact of Tukey outlier deletion also takes into account the removal of the two Part D appeals measures (Appeals Auto-Forward and Appeals Upheld) and the Part C measure Adult BMI Assessment in the simulations, because these measures will be removed starting with the 2022 Star Ratings. In general, there tend to be more outliers on the lower end of measure scores. As a result, the 1 to 2 star thresholds often increased in the simulations when outliers were removed compared to the other thresholds which were not as impacted.

The effect of Tukey outlier deletion would create a savings of $808.9 million for 2024, increasing to $1,449.2 million by 2030. Given the significant drawbacks of trimming, we are proposing to add Tukey outer fence outlier deletion to the clustering methodology for non-CAHPS measures. We request commenter feedback on Tukey outer fence outlier deletion as an additional step prior to hierarchal clustering. In the first year that this would be implemented, the prior year's thresholds would be rerun, including mean resampling and Tukey outer fence deletion so that the guardrails would be applied such that there is consistency between the years. We propose to amend §§ 422.162 and 423.182 to add a definition of the outlier methodology and amend §§ 422.166(a)(2) and 423.186(a)(2) to apply the outlier deletion using that methodology prior to applying mean resampling with hierarchal clustering. We welcome comments on this proposal.

4. Contract Consolidations (§§ 422.162(b)(3), 423.182(b)(3))

The process for calculating the measure scores for contracts that consolidate is specified as a series of steps at §§ 422.162(b)(3) and 423.182(b)(3). We propose to add a rule to account for instances when the measure score is missing from the consumed or surviving contract(s) due to a data integrity issue as described at §§ 422.164(g)(1)(i) and (ii) and 423.184(g)(1)(i) and (ii). CMS proposes to assign a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score. These rules would apply for contract consolidations approved on or after January 1, 2021. First, we propose minor technical changes to the regulation text in §§ 422.162(b)(3)(iv)(A) and (B) and 423.182(b)(3)(ii)(A) and (B) to improve the clarity of the regulation text. Second, we propose to redesignate the current regulation text (with the technical changes) as new paragraphs (b)(3)(iv)(A)(*1*) and (b)(3)(iv)(B)(*1*) and (b)(3)(ii)(A)(*1*) and (b)(3)(ii)(B)(*1*) of these regulations and to codify this new rule for contract consolidations approved on or after January 1, 2021 as §§ 422.162(b)(3)(iv)(A)(*2*) and (b)(3)(iv)(B)(*2*) and 423.182(b)(3)(ii)(A)(*2*) and (b)(3)(ii)(B)(*2*). We welcome comments on this proposal. We also propose an additional rule at §§ 422.164(g)(1)(iii)(A) and 423.184(g)(1)(iii)(A) to address how the Timeliness Monitoring Project

(TMP) or audit data are handled when two or more contracts consolidate. We propose to add that the TMP or audit data will be combined for the consumed and surviving contracts before carrying out the methodology as provided in paragraphs B through N (for Part C) and paragraphs B through L (for Part D). These rules would apply for contract consolidations approved on or after January 1, 2021. We propose to redesignate the current regulation text as new paragraphs (g)(1)(iii)(A)(*1*) and (g)(1)(ii)(A)(*1*) of these regulations and to codify this new rule for contract consolidations on or after January 1, 2021 as paragraphs (g)(1)(iii)(A)(*2*) and (g)(1)(ii)(A)(*2*). We welcome comments on this proposal.

5. Adding, Updating, and Removing Measures (§§ 422.164, 423.184)

The regulations at §§ 422.164 and 423.184 specify the criteria and procedure for adding, updating, and removing measures for the Star Ratings program. Due to the regular updates and revisions made to measures, CMS does not codify a list in regulation text of the measures (and specifications) adopted for the MA and Part D Star Ratings Program (83 FR 16537). CMS lists the measures used for the Star Ratings each year in the Technical Notes or similar guidance document with publication of the Star Ratings. In this rule, CMS is proposing measure changes to the Star Ratings program for performance periods beginning on or after January 1, 2021.

a. Proposed Measure Removal

CMS proposes to remove the Rheumatoid Arthritis Management measure from the Part C Star Ratings for the 2021 measurement year and the 2023 Star Ratings. The measure steward, NCQA, is retiring this measure from the HEDIS measurement set for the 2021 measurement year due to multiple concerns. For example, there are concerns that the performance on the measure may not reflect the rate at which members get anti-rheumatic drug therapy because sometimes these medications are covered by Patient Assistance Programs, which do not generate claims. In terms of the measure construction, the measure assesses only if members received a disease-modifying anti-rheumatic drug once during the measurement year, rather than assessing if members remain adherent to the medication. Additionally, it is unclear, based on the evidence, whether patients in remission should remain on these medications. Since NCQA plans to retire this measure from the HEDIS measurement set, CMS proposes to remove it starting with the 2023 Star Ratings. We welcome comments on this proposal.

b. Proposed Measure Updates

(1) Updates to the Improving or Maintaining Physical Health Measure and Improving or Maintaining Mental Health Measure From the HOS (Part C).

In accordance with § 422.164(d)(2), we are proposing substantive updates to two measures from the Medicare Health Outcomes Survey (HOS): The Improving or Maintaining Physical Health (PCS) measure and Improving or Maintaining Mental Health (MCS) measure.

First, we are proposing to change the case-mix adjustment for the measures. Case-mix adjustment (CMA) is critical to measuring and comparing longitudinal changes in the physical and mental health of beneficiaries across MA contracts through the PCS and MCS measures. To ensure fair and comparable contract-level scores, it is important to account for differences in beneficiary characteristics across contracts for these two measures. CMS proposes to modify the current approach for adjusting for differences in the case-mix of enrollees across contracts. The proposed approach would improve the case-mix model performance and simplify the implementation and interpretation of case-mix results when particular case-mix variables, such as household income, are missing. The current method for handling missing case-mix variables results in a reduced number of case-mix variables used for a beneficiary because it does not use any of the case-mix variables in a group of adjusters if one is missing from the group (see Medicare Part C & D Star Ratings Technical Notes, Attachment A for a full description of the current HOS case-mix methodology). This ''all-or-nothing'' approach for each group of adjusters may not be as efficient as alternative approaches for handling missing case-mix adjusters. Under the proposed change, when an adjuster is missing for a beneficiary, it would be replaced with the mean value for that adjuster for other beneficiaries in the same contract who also supply data for the PCS/MCS measures. This proposed approach has been used for the Medicare Advantage and Prescription Drug Plan CAHPS surveys for many years (see the 2020 Medicare Part C & D Star Ratings Technical Notes Attachment A for a description of the CAHPS case-mix methodology). In simulation models, this approach either outperformed the current approach for predicting outcomes or matched the current approach. The proposed approach is also easier to implement than the current approach because replacing the missing adjuster values with the contract mean scores for those adjusters rather than deleting the grouping of adjusters is less burdensome because it involves fewer steps and is easier to replicate and understand.

Second, we are proposing to increase the minimum required denominator from 30 to 100 for the two measures. The proposed increase to the minimum denominator would bring these measures into alignment with the denominator requirements for the HEDIS measures that come from the HOS survey and increase the reliability for these measures compared to the current reporting threshold of 30. We welcome comments on these proposals.

(2) Statin Use in Persons With Diabetes (Part D)

In the 2019 Call Letter, we proposed and finalized the addition of the Statin Use in Persons with Diabetes (SUPD) measure to the 2019 Star Ratings with a weight of 1 as a first year measure, then to have an increased weight of 3 as an intermediate outcome measure, starting with the 2020 Star Ratings. CMS did not increase the weight of this measure in the 2020 Star Ratings in response to the majority of comments to the Draft 2020 Call Letter opposing CMS's categorization of the measure as an intermediate outcome measure. The commenters presented a number of reasons for reclassifying the SUPD measure as a process measure, and we generally agree. For example, commenters noted that the Part C Statin Therapy for Patients with Cardiovascular Disease measure is similar to the SUPD and is a process measure. Also, commented pointed out that the SUPD measure specifications require two diabetes medication fills to qualify for the denominator, while only a single fill of a statin drug is required to be counted in the numerator. Commenters believed that this does not indicate a level of medication compliance needed to categorize it as an intermediate outcome measure. Furthermore, in a Frequently Asked Question (FAQ), the Pharmacy Quality Alliance clarified that ''The PQA SUPD measure is classified as a process measure. This aligns with the NQF definition for process measures, as prescribing a statin is a ''step that should be followed to provide good care'' rather than an outcome of such

care. [44] The FAQ can be found at *https://www.pqaalliance.org/measures-overview#supd.*

We finalized the SUPD measure with the intermediate outcome classification in the April 2019 final rule for the 2021 Star Ratings but no longer believe that is the appropriate classification. We propose to modify the classification of the SUPD measure category from an intermediate outcome classification to be a process measure, starting with the 2023 Star Ratings. This aligns with CMS's definition in the April 2019 final rule that process measures capture the health care services provided to beneficiaries which can assist in maintaining, monitoring, or improving their health status. We welcome comments on this proposal.

c. Proposed Measure Additions

As discussed in the April 2018 final rule (83 FR 16440), CMS stated that we anticipate that new measures will be added over time. Sections 422.164(c)(3) and (4) and 423.184(c)(3) and (4) provide that new measures would be reported on the display page for a minimum of 2 years before being added to the Star Ratings program; and new Star Ratings measures will be proposed and finalized through rulemaking. CMS is working with NCQA to expand efforts to better evaluate a plan's success at effectively transitioning care from a clinical setting to home. In the 2019 Call Letter, CMS discussed two potential new Part C measures and finalized these two measures in the 2020 Call Letter. CMS is proposing to add the HEDIS Transitions of Care and the HEDIS Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions measures to the 2023 Star Ratings covering the contract year 2021 Performance Period. We are planning to display these new Part C measures on the display page for 3 years prior to adding them to the Star Ratings program, starting with the 2020 display page.

Since the Part C and D measures are now proposed and finalized through rulemaking, going forward we intend to follow the pre-rulemaking process that is used in other CMS programs. Section 3014 of the Affordable Care Act created a new section 1890A of the Social Security Act, which requires that HHS establish a federal pre-rulemaking process for the selection of quality and efficiency measures for use by HHS. HHS is required to convene multi-stakeholder groups to provide consensus-based input for the annual Measures under Consideration List. Both of these proposed measures were submitted through the Measures under Consideration process and were reviewed by the Measure Applications Partnership which is a multi-stakeholder partnership that provides recommendations to HHS on the selection of quality and efficiency measures for CMS programs.

(1) Transitions of Care (Part C)

The HEDIS Transitions of Care measure is the percent of discharges for members 18 years or older who have each of the four indicators during the measurement year: (1) notification of inpatient admission and discharge; (2) receipt of discharge information; (3) patient engagement after inpatient discharge; and (4) medication reconciliation post discharge.

Based on stakeholder input, NCQA is considering making a few non-substantive measure specification changes. The first considered change, for all measure indicators, is to broaden the forms of communications from one outpatient medical record to other forms of communication such as admission, discharge, and transfer record feeds, health information exchanges, and shared electronic medical records. The second is to change the notifications and receipts from 'on the day of admission or discharge or the following day' to 'on the day of admission or discharge or within the following two calendar days.' A third is to change one of the six criteria of the Receipt of Discharge Information indicator from 'instructions to the primary care providers or ongoing care provider for patient care' to 'instructions for patient care post-discharge.' If these updates are implemented we believe all of these changes are non-substantive since they add additional tests that would meet the numerator requirements as described at § 422.164(d)(1)(iv)(A); add alternative data sources as described at § 422.164(d)(1)(v); and do not change the population covered by the measure.

The intent of this measure is to improve the quality of care transitions from an inpatient setting to home, as effective transitioning will help reduce hospital readmissions, costs, and adverse events. The Transitions of Care measure excludes members in hospice and is based on the number of discharges, not members. We are proposing to add this measure to the Star Ratings in 2023 covering the contract year 2021 measurement period.

(2) Follow-Up After Emergency Department Visit for Patients With Multiple Chronic Conditions (Part C)

CMS is proposing to add a new HEDIS measure assessing follow-up care provided after an emergency department (ED) visit for patients with multiple chronic conditions. This measure is the percentage of ED visits for members 18 years and older who have high-risk multiple chronic conditions who had a follow-up service within 7 days of the ED visit between January 1 and December 24 of the measurement year. The measure is based on ED visits, not members. Eligible members must have two or more of the following chronic conditions: Chronic obstructive pulmonary disease (COPD) and asthma; Alzheimer's disease and related disorders; chronic kidney disease; depression; heart failure; acute myocardial infarction; atrial fibrillation; and stroke and transient ischemic attack. The following meet the criteria to qualify as a follow-up service for purposes of the measure: An outpatient visit (with or without telehealth modifier); a behavioral health visit; a telephone visit; transitional care management services; case management visits; and complex care management. Patients with multiple chronic conditions are more likely to have complex care needs, and follow-up after an acute event, like an ED visit, can help prevent the development of more severe complications. We are proposing to add this measure to the 2023 Star Ratings covering the contract year 2021 measurement period.

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[44] Process measures: These types of measures focus on whether actions that have been shown to benefit patients have been followed. Examples include: Whether patients with diabetes receive HbA1c testing during the measurement period; whether adolescents have received recommended immunizations; or whether stroke patients have received clot-busting medications in a timely manner.

TABLE 3: PROPOSED NEW AND REVISED INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2021

The measure descriptions listed in this table are high-level descriptions. The Star Ratings measure specifications supporting document, *Medicare Part C & D Star Ratings Technical Notes*, provides detailed specifications for each measure. Detailed specifications include, where appropriate, more specific identification of a measure's: (1) numerator, (2) denominator, (3) calculation, (4) timeframe, (5) case-mix adjustment, and (6) exclusions. The Technical Notes document is updated annually. In addition, where appropriate, the Data Source descriptions listed in this table reference the technical manuals of the measure stewards. The annual Star Ratings are produced in the fall of the prior year. For example, Star Ratings for the year 2020 are produced in the fall of 2019. If a measurement period is listed as 'the calendar year 2 years prior to the Star Ratings year' and the Star Ratings year is 2020, the measurement period is referencing the 1/1/2018-12/31/2018 period.

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Ratings	Reporting Requirements by Contract Type
Part C Measure								
Transitions of Care (TRC)	Percentage of discharges for members 18 years of age and older who had each of the following: 1) notification of admission and post-discharge: 2) receipt of discharge information, 3) patient engagement, and 4) medication reconciliation.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	Not Available	Clustering	MA-PD and MA-only
Follow-up after ED Visit for Patients with Multiple	Percentage of emergency department (ED) visits for members 18 years and older who have multiple high-risk	Managing Chronic (Long	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the	Not Available	Clustering	MA-PD and MA-only

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Ratings	Reporting Requirements by Contract Type
Chronic Conditions (FMC)	chronic conditions who had a follow-up service within 7 days of the ED visit. Eligible members must have two or more of the following chronic conditions: COPD and asthma; Alzheimer's disease and related disorders; chronic kidney disease; depression; heart failure; acute myocardial infarction; atrial fibrillation; and stroke and transient ischemic attack.	Term) Conditions			Star Ratings year			
Part D Measure								
Statin Use in Persons with Diabetes (SUPD)	Percent of the number of plan members 40-75 years old who were dispensed at least two diabetes medication fills and received a statin medication fill.	Drug Safety and Accuracy of Drug Pricing	Process Measure Weight of 1	Prescription Drug Event (PDE) data	The calendar year 2 years prior to the Star Ratings year	#2712	Clustering	MA-PD and PDP

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We welcome comments on these proposals.

6. Measure Weights (§§ 422.166(e), 423.186(e))

As finalized in the April 2018 final rule, beginning with the 2021 Star Ratings, §§ 422.166(e)(1)(iii) and (iv) and 423.186(e)(1)(iii) and (iv) provide the weight of 2 for both patient experience/complaints and access measures. We stated in the April 2018 final rule (83 FR 16575–16576) that given the importance of hearing the voice of patients when evaluating the quality of care provided, CMS intends to further increase the weight of patient experience/complaints and access measures in the future. The measures include the patient experience of care measures collected through the CAHPS survey, Members Choosing to Leave the Plan, Appeals, Call Center, and Complaints measures. The majority of the measures impacted by the proposed weight change are the CAHPS measures that focus on critical aspects of care from the perspective of patients such as access and care coordination issues. The experience of care measures focus on matters that patients themselves say are important to them and for which they are the best and/or only source of information.

The proposed increase in the weight does not impact the assignment of stars at the measure level, just the calculation of the overall and summary ratings, and will not impact the distribution of stars which varies for each of these measures. The statistical reliability of the CAHPS measures is high, exceeding standards for quality measurement so that higher star categories correspond to meaningfully better performance (generally, reliabilities of 0.7 or more are considered high for a quality measure).[45] The inter-unit reliability of the CAHPS measures range from 0.7638 for Customer Service to 0.9215 for Rating of Health Plan measure. The reliability for the other measures is as follows: Care Coordination is 0.8155, Getting Appointments and Care Quickly is 0.9059, Getting Needed Care is 0.8543, Getting Needed Prescription Drugs is 0.7895, Rating of Drug Plan is 0.8937, and Rating of Health Care Quality is 0.8263.

CMS has pledged to put patients first and to empower patients to work with their providers to make health care decisions that are best for them. To best meet the needs of beneficiaries, CMS believes we must listen to their perceptions of care, as well as ensure that they have access to needed care. Thus, CMS proposes to modify §§ 422.166(e) and 423.186(e) at paragraphs (e)(1)(iii) and (iv) to increase the weight of patient experience/complaints and access measures to 4 to further emphasize the importance of patient experience/complaints and access issues. If both Tukey outlier deletion and increasing the weight of patient experience/complaints and access measures are adopted, the net savings would be $368.1 million for 2024, increasing to $999.4 million for 2030.

7. Extreme and Uncontrollable Circumstances (§§ 422.166(i), 423.186(i))

As we have gained more experience with disasters and applying the disaster policy over the last couple of years, we are soliciting additional feedback on the disaster policy for contracts impacted across multiple years. As we stated in the April 2019 final rule, we are concerned about looking back too many years for contracts affected by disasters multiple years in a row; we are also concerned about including too many measurement periods in 1 year of Star Ratings. We also must consider operational feasibility, because using different thresholds for contracts affected by disasters in different ways would be very complicated for administration and for providing the necessary transparency to MA organizations, Part D plan sponsors, and beneficiaries who use and rely on the Star Ratings. We must balance these concerns about using older data with concerns about using data based on performance that has been impacted by consecutive disasters.

In striking a balance, we finalized in the April 2019 final rule a policy starting with the 2022 Star Ratings for contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas that were affected by disasters that began in 1 year and were also affected by disasters that began in the previous year. Such multiple year-affected contracts will receive the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure. For example, if a multiple year-affected contract reverts to the 2021 Star Rating on a given measure in the 2022 Star Ratings, the 2021 Star Rating is not used in determining the 2023 Star Rating; rather, the 2023 Star Rating is compared to what the 2022 Star Rating would have been absent any disaster adjustments.

The rule for treatment of multiple year-affected contracts was established to limit the age of data that will be carried forward into the Star Ratings. We use the measure score associated with the year with the higher measure Star Rating regardless of whether the score is higher or lower that year. We finalized this policy to address when contracts are affected by separate extreme and uncontrollable circumstances that occur in successive years for the adjustments to CAHPS, HOS, HEDIS, and other measures. The provisions at §§ 422.166(i)(2)(v), (i)(3)(v), (i)(4)(vi), and (i)(6)(iv) and 423.186(i)(2)(v) and (i)(4)(iv) include this rule for how ratings for these measures are adjusted in these circumstances. We solicit comment on this policy and whether further adjustments are necessary.

In addition, the regulation we finalized to govern adjustments to a contract's Star Rating based on extreme and uncontrollable circumstances includes a provision to address when an affected contract has missing data. This provision was finalized at §§ 422.166(i)(8) and 423.186(i)(6) and provides that for an affected contract that has missing data in the current or previous year, the final measure rating comes from the current year unless an exemption described elsewhere in the regulation applies. We propose to modify §§ 422.166(i)(8) and 423.186(i)(6) to add new text at the end of the current regulation text to clarify that missing data includes data where there is a data integrity issue as defined at § 422.164(g)(1) and 423.184(g)(1). Under this proposal, when there is a data integrity issue in the current or previous year, the final measure rating comes from the current year.

8. Quality Bonus Payment Rules

The Affordable Care Act amended sections 1853(n) and 1853(o) of the Act to require CMS to make quality bonus payments (QBPs) to Medicare Advantage (MA) organizations that achieve at least 4 stars in a 5-star Quality Rating system. The Affordable Care Act also amended section 1854(b)(1)(C) of the Act to change the share of savings that MA organizations must provide to enrollees as the beneficiary rebate, mandating that the level of rebate is tied to the level of an MA organization's Quality Bonus Payment (QBP) rating. As a result, beginning in 2012, quality as measured by the 5-star Quality Rating System directly affected the monthly payment amount MA organizations receive from CMS. At the time the QBPs were implemented, CMS codified at § 422.260

[45] *https://www.rand.org/content/dam/rand/pubs/technical_reports/2009/RAND_TR653.pdf.*

an administrative review process available to MA organizations for payment determinations based on the quality bonuses. Historically, every November CMS has released the preliminary QBP ratings for MA contracts to review their ratings and to submit an appeal if they believe there is a calculation error or incorrect data are used as described at § 422.260(c).

In the April 2018 final rule, we codified at § 422.160(b)(2) that the ratings calculated and assigned under this subpart are used to provide quality ratings on a 5-star rating system used in determining QBPs and rebate retention allowances. Historically, the QBP rating rules have been announced through the Advance Notice and Rate Announcement since section 1853(b) of the Act authorizes an advance notice and rate announcement to solicit comment for proposed changes and announce changes to the MA payment methodology. As we have over the last couple of years codified in regulation the methodology for the Star Ratings, we are also proposing to clarify the rules around assigning QBP ratings, codify the rules around assigning QBP ratings for new contracts under existing parent organizations, and amend the definition of new MA plan that is codified at § 422.252 by clarifying how we apply the definition. Our proposal would codify current policy (for how we have historically assigned QBP ratings) without any changes.

Historically, for contracts that receive a numeric Star Rating, the final QBP rating released in April for the following contract year would be the contract's highest rating as defined at § 422.162(a). Section 422.260(a) states that the QBP determinations are made based on the overall rating for MA–PDs and the Part C summary rating for MA-only contracts. For further clarification, we are proposing to add language at § 422.162(b)(4) stating that for contracts that receive a numeric Star Rating, the final QBP rating is released in April of each year for the following contract year and that the QBP rating is the contract's highest rating, as that term is defined at § 422.162(a). We also propose to clarify in the regulation text that QBP rating is the contract's highest rating from the Star Ratings published by CMS in October of the calendar year that is 2 years before the contract year to which the QBP rating applies. For example, the 2020 QBPs were released in April 2019 and based on the Star Ratings published in October 2018. For MA contracts that offer Part D, the QBP rating would be the numeric overall Star Rating. For MA contracts that do not offer Part D (MA-only, MSA, and some PFFS contracts), the QBP rating would be the numeric Part C summary rating. We also propose adding language at § 422.160(b)(2)(ii) clarifying that the contract QBP rating is applied to each plan benefit package under the contract.

If a contract does not have sufficient data to calculate and assign Star Ratings for a given year because it is a new MA plan or low enrollment contract, § 422.166(d)(2)(v) provides the rules for assigning a QBP rating. That regulation references the definitions at § 422.252. We propose to amend the definition at § 422.252 for new MA plans by clarifying how we apply the definition as follows: *New MA plan* means a plan that meets the following: (1) Is offered under a new MA contract; and (2) is offered under an MA contract that is held by a parent organization defined at § 422.2 that has not had an MA contract in the prior 3 years.

We also propose to add rules at § 422.166(d)(2)(vi) for contracts that do not have sufficient data to calculate and assign ratings and do not meet the definition of low enrollment or new MA plans at § 422.252. Our proposal would codify the policy that has been in place since the 2012 Rate Announcement: any new contract under an existing parent organization that has had MA contract(s) with CMS in the previous 3 years receives an enrollment-weighted average of the Star Ratings earned by the parent organization's existing MA contracts. We intend for this policy to continue uninterrupted so that the calculation of QBPs remains stable and transparent to stakeholders.

We propose to add at § 422.166(d)(2)(vi)(A) that any new contract under an existing parent organization that has other MA contracts with numeric Star Ratings in November (when the preliminary QBP ratings are calculated for the contract year that begins 14 months later) would be assigned the enrollment-weighted average of the highest Star Rating of all other MA contracts under the parent organization that will be active as of April the following year. The Star Ratings used in this calculation would be the rounded stars (to the whole or half star) that are publicly displayed. For example, for the 2021 QBPs, for any new contracts under an existing parent organization, we would apply this rule as follows:

(i) We identify the parent organization of the new contract in November 2019.

(ii) We identify the MA contracts held by that parent organization in November 2019, when the preliminary 2021 QBP ratings are posted for review. For preliminary QBP ratings, we use the numeric Star Ratings for those MA contracts that were held by the parent organization in November 2019 that we anticipate to still be in existence and held by that parent organization in April 2020.

(iii) Using the enrollment in those other MA contracts as of November 2019, we calculate the enrollment-weighted average of the highest Star Rating(s) of those MA contracts.

(iv) In April 2020, we update the enrollment-weighted average rating based on any changes to the parent organization of existing contracts, using the November 2019 enrollment in the contracts. The enrollment-weighted average rating would include the ratings of any contract(s) that the parent organization acquired since November 2019. This enrollment-weighted average would be used as the 2021 QBP rating for the new MA contract under the parent organization for payment in 2021. This final QBP rating would be released to the MA organization for the new contract in April of 2020.

We propose to add at § 422.166(d)(2)(vi)(B) that if a new contract is under a parent organization that does not have any other MA contracts with numeric Star Ratings in November, CMS would look at the MA Star Ratings for the previous 3 years. The QBP rating would be the enrollment-weighted average of the MA contracts' highest Star Ratings from the most recent year that had been rated for that parent organization. For example, if in November 2019 there are no other MA contracts under the parent organization with numeric 2020 Star Ratings, we would go back first to the 2019 Star Ratings and then the 2018 Star Ratings. If there were MA contract(s) in the parent organization with Star Ratings in any of the previous 3 years, the QBP rating would be the enrollment-weighted average of the MA contracts' highest Star Ratings from the most recent year rated. The Star Ratings used in this calculation would be the rounded stars (to the whole or half star) that are publicly reported at some point on *www.medicare.gov.*

For example, for the 2021 QBPs, for any new contract(s) under a parent organization that has no MA contracts in November 2019, we would apply this rule as follows:

(i) We identify the MA contracts held by that parent organization in November 2018. If the parent organization had other MA contracts in November 2018, we use the numeric Star Ratings issued in October 2018 for those MA contracts that were held by the parent organization in November 2018.

(ii) Using the enrollment in those other MA contracts as of November

2018, we would calculate the enrollment-weighted average of the highest Star Rating(s) of those MA contracts.

(iii) This enrollment-weighted average would be used as the 2021 QBP rating for the new MA contract for that parent organization, for payment in 2021. This final QBP rating would be released to the MA organization for the new contract in April of 2020.

For the 2021 QBPs, for any new contract(s) under a parent organization that has no MA contracts in November 2018 and 2019, we would apply this rule as follows:

(i) We identify the MA contracts held by that parent organization in November 2017. If the parent organization had other MA contracts in November 2017, we use the numeric Star Ratings for those MA contracts that were held by the parent organization in November 2017.

(ii) Using the enrollment in those other MA contracts as of November 2017, we calculate the enrollment-weighted average of the highest Star Rating(s) of those MA contracts.

(iii) This would be used as the 2021 QBP rating for the new MA contract for payment in 2021. This final QBP rating would be released to the MA organization for the new contract in April of 2020.

If there were no MA contract(s) in the parent organization with numeric Star Ratings in the previous 3 years, the contract is rated as a new MA plan in accordance with § 422.258 (for QBP purposes) and § 422.166(d)(2)(v) (for other purposes).

We propose the rules for calculating the enrollment-weighted average and addressing changes in parent organizations in paragraphs (d)(2)(iv)(C) through (E). We propose to add at § 422.166(d)(2)(vi)(C) that the enrollment used in the enrollment-weighted calculations is the November enrollment in the year the Star Ratings are released. The enrollment data are currently posted publicly at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html.*

We also propose at § 422.166(d)(2)(vi)(D) that the QBP ratings would be updated for any changes in a contract's parent organization prior to the release of the final QBP ratings in April of each year. The same rules described at § 422.166(d)(2)(vi)(A), (B), and (C) would be applied to the new contract using the new parent organization information. For example, for the 2021 QBPs, in April 2020 when the final QBP ratings are released, the enrollment-weighted average rating would include the ratings of any MA contract(s) that the parent organization acquired since November 2019. Thus, if a parent organization buys an existing contract it would be included in the enrollment-weighted average. We are also proposing at § 422.166(d)(2)(vi)(E) to codify our current practice that once the QBP ratings are finalized in April of each year for the following contract year, no additional parent organization changes are possible for QBP purposes.

We welcome comments on this proposal.

F. Permitting a Second, ''Preferred'', Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

1. Overview and Summary

Section 1860D–2(b)(2) of the Act, which establishes the parameters of the Part D program's Defined Standard benefit, allows for alternative benefit designs that are actuarially equivalent to the Defined Standard, including the use of tiered formularies. Although not required, Part D sponsors are permitted to include a specialty tier in their plan design. Use of a specialty tier provides the opportunity for Part D sponsors to manage high-cost drugs apart from tiers that have less expensive drugs.

CMS's policy for the specialty tier has aimed to strike the appropriate balance between plan flexibility and Part D enrollee access to drugs, consistent with our statutory authority. Section 1860D–2(b) of the Act requires that a plan design be actuarially equivalent to the Defined Standard benefit. Permitting tiering exceptions to allow Part D enrollees to obtain drugs on specialty tiers at a lower cost sharing applicable to non-specialty tiers could result in increased Part D premiums as well as increased cost sharing for non-specialty tiers. In other words, the ability to get lower cost sharing on specialty drugs through these kinds of exceptions means that costs would have to go up elsewhere—such as by increasing the cost-sharing on generic drug tiers—in order to keep the benefit design actuarially equivalent. Section 1860D–4(g)(2) of the Act grants CMS authority to establish guidelines under which Part D enrollees may request exceptions to tiered cost-sharing structures. Accordingly, we have developed a minimum dollar-per-month threshold amount to determine which drugs are eligible, based on relative high cost, for inclusion on the specialty tier,[46] and implemented a regulation (most recently § 423.578(a)(6)(iii)) permitting Part D sponsors to exempt drugs placed on the specialty tier from their tiering exceptions process. To prevent discriminatory formulary structures, in particular to protect Part D enrollees with certain disease types that are treated only by specialty tier-eligible drugs, our guidance[47] has set the maximum allowable cost sharing for drugs on the specialty tier between 25 and 33 percent coinsurance (25/33 percent).

We have not previously permitted Part D sponsors to structure their plans with more than one specialty tier. Pointing to factors such as the introduction of biosimilar biological products to the market[48] and recent higher pricing of some generic drugs relative to brand drug costs, some stakeholders requested that we reconsider this policy. They posited, for instance, that creating an additional specialty tier could improve the ability of Part D sponsors to negotiate with pharmaceutical manufacturers to help lower the prices of high-cost Part D drugs. Moreover, in its June 2016 Report to Congress (available at *http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf*), the Medicare Payment Advisory Commission (MedPAC) suggested that having two specialty tiers with differential cost sharing could potentially encourage the use of lower-cost biosimilar (or interchangeable, when available) biological products and encourage competition among existing specialty Part D drugs. More recently, some commenters on our Draft 2020 Call Letter (available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents-Items/2020Advance.html*) took the

[46] See, for instance, Draft 2020 Call Letter, pages 178–179 (available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf*), and Final 2020 Call Letter, page 208 (available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf*).

[47] See section 30.2.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf* and page 21 of the 2020 Bid Submission User Manual, Chapter 7: Plan Benefit Package Rx Drugs Section. The Bid Submission User Manual for 2020 is available at the following pathway after logging into the Health Plan Management System (HPMS): Plan Bids > Bid Submission > Contract Year 2020 > View Documentation > Bid Submission User Manual.

[48] See the April 2018 final rule for more background on biosimilar biological products (83 FR 16610).

opportunity to advocate for a second specialty tier.

Improving Part D enrollee access to needed drugs and lowering drug costs are central goals for CMS. Accordingly, in the hopes of providing flexibility that will promote these goals, we propose to allow Part D sponsors to establish up to two specialty tiers and design an exceptions process that exempts Part D drugs on these tiers from tiering exceptions to non-specialty tiers. Under our proposal, Part D sponsors would have the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the ingredient cost threshold established according to the methodology we are proposing and the requirements of the CMS formulary review and approval process under § 423.120(b)(2). To maintain Part D enrollee protections, we are proposing to codify a maximum allowable cost sharing that would apply to a single specialty tier, or, if a Part D sponsor has a plan with two specialty tiers, to the higher cost-sharing specialty tier. Further, we propose to require that if a Part D sponsor has a plan with two specialty tiers, one must be a ''preferred'' tier that offers lower cost sharing than the higher cost sharing tier, which is subject to the proposed maximum allowable specialty-tier cost sharing. We note that we are not proposing any revisions to § 423.578(c)(3)(ii), which requires Part D sponsors to provide coverage for a drug for which a tiering exception was approved at the cost sharing that applies to the preferred alternative. We are proposing that the exemption from tiering exceptions for specialty tier drugs, at § 423.578(a)(6)(iii), would apply only to tiering exceptions to non-specialty tiers (meaning, when the tiering exception request is for the specialty tier drug to be covered at a cost-sharing level that applies to a non-specialty tier). Under our proposal, we would require Part D sponsors to permit tiering exception requests for drugs on the higher cost-sharing specialty tier to the lower cost-sharing specialty tier.

To improve transparency, we propose to codify current methodologies for cost sharing and calculations relative to the specialty tier, with some modifications. First, we propose to codify a maximum allowable cost sharing permitted for the specialty tiers of between 25 percent and 33 percent, depending on whether the plan includes a deductible, as described further in section V.F.4. of this proposed rule. We also propose to determine the specialty-tier cost threshold—meaning whether the drug has costs high enough to qualify for specialty tier placement—based on a 30-day equivalent supply. Additionally, we propose to base the determination of the specialty-tier cost threshold on the ingredient cost reported on the PDE. This would be a change from our current policy, which uses the negotiated price reflected on the PDE. Under our proposal, the specialty-tier cost threshold would apply to both specialty tiers. To respond to comments on our Draft 2020 Call Letter requesting that the specialty-tier cost threshold be increased regularly, we also propose to maintain a specialty-tier cost threshold that is set at a level that, in general, reflects Part D drugs with monthly ingredient costs that are in the top one percent of all monthly ingredient costs, as described further in section V.F.6. of this proposed rule. We propose to adjust the threshold, in an increment of not less than ten percent, rounded to the nearest $10, when an annual analysis of PDEs shows that recalibration of the specialty-tier cost threshold is necessary to continue to reflect only Part D drugs with the top one percent of monthly ingredient costs. We propose to annually determine whether the adjustment would be triggered and announce the specialty-tier cost threshold.

2. A Second, ''Preferred'', Specialty Tier

Placement on the specialty tier can play an important role in maintaining lower drug prices. Non-preferred brand or other non-preferred, non-specialty tiers frequently have cost sharing equal to as much as 50 percent coinsurance. This means that Part D enrollees would pay considerably more after application of coinsurance for a high-cost drug if it appeared on a non-preferred tier with, for instance, 50 percent cost sharing as opposed to placement on the specialty tier, which (as discussed later) has been subject to lower cost sharing requirements. For this reason we reject the suggestion of some commenters on our Draft 2020 Call Letter that we eliminate the specialty tier altogether. To the opposite effect, as noted previously, other stakeholders, including MedPAC, have recommended we permit Part D sponsors to create a second specialty tier. Stakeholders favoring this approach have posited that this change would: (1) Improve the ability of Part D sponsors and pharmacy benefit managers (PBMs) to negotiate better rebates with manufacturers by enabling them to establish a preferred specialty tier that distinguishes between high-cost drugs and effectively encourages the use of preferred specialty drugs; (2) reduce costs for Part D enrollees, not only through direct cost-sharing savings associated with a lower-cost, ''preferred'' specialty tier, but also through the lowered premiums for all Part D enrollees that could result from better rebates on specialty tier drugs; and (3) reduce costs to CMS directly through lower drug costs because lower cost sharing would delay a Part D enrollee's entry into the catastrophic phase of the benefit in which the government is responsible for 80 percent of the costs.

Consistent with CMS' ongoing efforts to implement new strategies that can help lower drug prices and increase competition, CMS now proposes to permit Part D sponsors to have up to two specialty tiers by permitting a new preferred specialty tier. However, driven by ongoing concerns over actuarial equivalence and discriminatory benefit designs, in order to strike the appropriate balance between plan flexibility and Part D enrollee access, CMS must also carefully weigh the following factors: (1) Tiering exceptions between the two specialty tiers or to other, non-specialty tiers; (2) the maximum allowable cost sharing for each specialty tier; and (3) tier composition (that is, the selection of Part D drugs for each specialty tier). The proposed regulatory text to allow up to two specialty tiers (which reflects CMS' consideration of these factors) and other related proposals are discussed in the following sections of this preamble.

3. Tiering Exceptions and Two Specialty Tiers

Section 1860D–4(g)(2) of the Act specifies that a beneficiary enrolled in a Part D plan offering a prescription drug benefit for Part D drugs through the use of a tiered formulary may request an exception to the Part D sponsor's tiered cost-sharing structure. Additionally, Part D sponsors are required under this section to create an exceptions process to handle such requests, consistent with guidelines established by CMS (see section 40.5.1 of Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, available at *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf*). However, section 1860D–4(g)(2) of the Act did not require tiering exceptions in every case, and even indicated that tiering exceptions might not be covered in every instance, by recognizing that non-preferred Part D drugs ''could be'' covered at the cost sharing applicable to preferred Part D drugs.

As noted earlier, the requirement that Part D plans be actuarially equivalent to

the Defined Standard benefit means that if Part D sponsors were required to permit Part D enrollees to obtain drugs on specialty tiers at non-specialty tier cost sharing, Part D sponsors might need to increase premiums and cost sharing for non-specialty tiers. To avoid such increased costs, in the Medicare Program; Medicare Prescription Drug Benefit Final Rule (hereinafter referred to as the January 2005 final rule, 70 FR 4193), CMS finalized § 423.578(a)(7), which provided that Part D sponsors with a tier for very high cost and unique items (in other words, a specialty tier), such as genomic and biotech products, could exempt such drugs from its tiering exception process (70 FR 4353).

In CMS's April 2018 final rule, CMS revised and redesignated § 423.578(a)(7) as new § 423.578(a)(6)(iii) to specify that if a Part D sponsor maintains a specialty tier, the Part D sponsor may design its exception process so that Part D drugs and biological products on the specialty tier are not eligible for a tiering exception. While the current policy does not require that Part D sponsors use a specialty tier that is exempt from tiering exceptions, we are aware that nearly all do.

Section 1860D–4(g)(2) of the Act stipulates that under an exception, a non-preferred Part D drug could be covered under the terms applicable for preferred Part D drugs if the prescribing provider determines that the preferred Part D drug for treatment of the same condition would not be as effective for the Part D enrollee, would have adverse effects for the Part D enrollee, or both. Thus, the statutory basis for approval of tiering exceptions requests is the presence of (a) clinically appropriate therapeutic alternative drug(s) or biological product(s) on a lower cost-sharing tier of the plan's formulary. Therefore, even if a Part D sponsor permitted tiering exceptions for Part D drugs on the specialty tier, tiering exceptions requests would not be approvable if the plan's formulary did not include any clinically appropriate therapeutic alternative Part D drugs on a lower cost-sharing tier. For example, suppose that reference biological product ''Biologic A'' and another biological product in the same class, ''Biologic B'' are both on the specialty tier with no clinically appropriate therapeutic alternative on a lower cost-sharing tier. If the Part D enrollee's prescriber were to write for Biologic A, and the prescriber were to request a tiering exception, because Biologic B, the clinically appropriate therapeutic alternative, is on the same tier as Biologic A, and not a lower cost-sharing tier, the tiering exception request would be denied. For further explanation of tiering exceptions requirements, please see § 423.578(a)(6).

Permitting Part D sponsors to exempt Part D drugs on a higher cost-sharing specialty tier from any tiering exceptions, even to a preferred specialty tier, would improve Part D sponsors' ability to negotiate better rebates. Nevertheless, unlike our justification for allowing Part D plans to exempt a specialty tier from tiering exceptions to lower cost non-specialty tiers, permitting tiering exceptions from the higher cost-sharing, specialty tier to the preferred specialty tier is less likely to lead to increased premiums or cost sharing to meet actuarial requirements because we are proposing to apply the same cost threshold to both specialty tiers. Our current belief is that improved negotiation alone is not sufficient to justify permitting Part D sponsors to exempt drugs on the higher cost-sharing, specialty tier from requests for tiering exceptions to the preferred specialty tier cost sharing. While as currently proposed, CMS would not require Part D sponsors to permit tiering exceptions from either specialty tier to lower, non-specialty tiers, our proposal would not change current regulations that require Part D sponsors to cover drugs for which a tiering exception was approved at the cost-sharing level that applies to the preferred alternative(s). This would mean that Part D sponsors would be required to permit tiering exceptions for Part D drugs from the higher cost-sharing, specialty tier to the preferred specialty tier if tiering exceptions requirements are met (for instance, when a Part D enrollee cannot take an applicable therapeutic alternative on the preferred specialty tier). Specifically, CMS proposes to amend § 423.578(a)(6)(iii) to specify that if a Part D sponsor maintains up to two specialty tiers, the Part D sponsor may design its exception process so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers. Consequently, the existing policy at § 423.578(c)(3)(ii) would require Part D sponsors to permit tiering exceptions between their two specialty tiers to provide coverage for the approved Part D drug on the higher cost-sharing, specialty tier that applies to preferred alternative Part D drugs on the lower cost-sharing, preferred specialty tier. While CMS would not require Part D sponsors to permit tiering exceptions to non-specialty tiers for Part D drugs on a specialty tier, nothing precludes a Part D sponsor from doing so, insofar as their plan benefit design remains actuarially equivalent to the Defined Standard benefit.

Alternatively, CMS could continue to permit Part D sponsors to exempt drugs on either specialty tier from tiering exceptions, as is provided under current regulations. We do not believe maintaining the current exemption would be discriminatory in light of CMS's proposal, discussed in the next section, to set a maximum allowable cost sharing (that is, 25/33 percent) for the higher cost-sharing, specialty tier and to also require the preferred specialty tier to have cost sharing below that maximum. If the proposed maximum allowable cost sharing is finalized, Part D enrollees would pay no more for a drug on either specialty tier than is the case under our current policy. And, as noted previously, maintaining the current exemption from tiering exceptions for all drugs on a specialty tier could allow Part D sponsors to negotiate better rebates. On the other hand, our proposal to require Part D sponsors with two specialty tiers to permit tiering exceptions from the higher-cost sharing to the lower-cost sharing, preferred specialty tier would provide a Part D enrollee protection when there is a therapeutic alternative on the preferred specialty tier that the Part D enrollee is unable to take. Accordingly, we invite comment on the benefits or drawbacks of maintaining the current policy under § 423.578(a)(6)(iii) that, if we were to finalize our proposal to permit Part D sponsors to have up to two specialty tiers, would apply to permit Part D sponsors to exempt drugs on a specialty tier from the tiering exceptions process altogether.

CMS notes that, as part of our proposed change at § 423.578(a)(6)(iii), we have proposed a technical change to remove the phrase ''and biological products.'' While the specialty tier usually includes biological products, in the context of the Part D program, biological products already are included in the definition of a Part D drug at § 423.100. Therefore the phrase ''Part D drugs and biological products'' is redundant and potentially misleading. Consequently, we propose to remove the phrase ''and biological products.''

To summarize, we are proposing to amend § 423.578(a)(6)(iii) to: (1) Reflect the possibility of a second specialty tier, permitting Part D sponsors to design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers and (2) remove the phrase ''and biological products.'' Additionally, we are proposing to maintain the existing policy at § 423.578(c)(3)(ii),

thereby requiring Part D sponsors to permit tiering exceptions between their two specialty tiers to provide coverage for the approved Part D drug on the higher cost-sharing specialty tier that applies to preferred alternative Part D drugs on the lower cost-sharing, preferred specialty tier. Additionally, if we finalize our proposal to permit Part D sponsors to maintain up to two specialty tiers, we solicit comment on maintaining the existing policy at § 423.578(a)(6)(iii), thereby permitting Part D sponsors to exempt drugs on either specialty tier from the tiering exceptions process altogether.

4. Maximum Allowable Cost Sharing and Two Specialty Tiers

At the start of the Part D program, when CMS provided Part D sponsors the option to exempt specialty tiers from the exceptions process, we remained concerned that removing this option for the specialty tier could potentially be discriminatory for Part D enrollees with certain diseases only treated by specialty tier-eligible drugs, and thus in conflict with the statutory directive under section 1860D–11(e)(2)(D) of the Act that CMS disapprove any ''design of the plan and its benefits (including any formulary and tiered formulary structure) that are likely to substantially discourage enrollment by certain part D eligible individuals under the plan.'' Using this authority, CMS aligned the cost-sharing limit for Part D drugs on the specialty tier with the Defined Standard benefit at section 1860D–2(b)(2)(A) of the Act. Consequently, CMS established a ''25/33 percent'' maximum allowable cost sharing for the specialty tier, meaning that we would approve cost sharing for the specialty tier of no more than 25 percent coinsurance after the standard deductible and before the initial coverage limit (ICL), or up to 33 percent coinsurance for plans with decreased or no deductible under alternative prescription drug coverage designs and before the ICL. In other words, under actuarially equivalent alternative prescription drug coverage designs, CMS allows the maximum allowable cost sharing for the specialty tier to be between 25 and 33 percent coinsurance if the Part D plan has a decreased deductible, such that the maximum allowable cost sharing equates to 25 percent coinsurance plus the standard deductible. CMS derived the maximum allowable cost sharing of 33 percent coinsurance for plans with no deductible under alternative prescription drug coverage by adding the allowable deductible to the 25 percent maximum allowable cost sharing between the deductible and initial coverage limit (ICL) and dividing the resultant value by the ICL.

For example, in 2006, under the Defined Standard benefit, the maximum deductible was $250, and the ICL was $2250. The maximum allowable cost sharing between the deductible and the ICL was 25 percent coinsurance. (This example uses contract year 2006 numbers for simplicity, but the concepts presented still apply to current guidance.)

$2250 ICL − $250 deductible = $2000 difference × 0.25 = $500 maximum allowable cost sharing after the deductible and before the ICL for specialty tier drugs in plans with the standard deductible.

$500 maximum (previous calculation) + $250 deductible = $750. Therefore, the maximum coinsurance before the ICL for specialty tier drugs in plans with no deductible is $750 divided by the $2250 ICL = 0.33, or 33 percent coinsurance.

Plans with deductibles between $0 and $250 were permitted to have maximum allowable cost sharing for specialty tier drugs between the deductible and the ICL of between $500 and $750 (that is, coinsurance between 25 and 33 percent) provided that such cost sharing added to the deductible was $750. For example, using contract year 2006 numbers, if the deductible was $100, the maximum coinsurance that the plan could charge for specialty tier drugs between the deductible and the ICL would have been approximately 30 percent:

$750 − $100 deductible = $650 maximum allowable cost sharing (that is, $650 + $100 = $750). Therefore the maximum coinsurance between the $100 deductible and the $2250 ICL ≈ 0.30, or 30 percent coinsurance; that is, $650 divided by $2150 ≈ 0.30, or 30 percent. (This 30 percent represents mathematical rounding from the actual calculated value.)

Because section 1860D–2(b)(2) of the Act requires that plan benefit designs be actuarially equivalent to the Defined Standard benefit, the cost sharing for high-cost drugs would likely increase without the use of a specialty tier. This is because often the specialty tier has lower cost sharing than non-preferred brand or other non-preferred, non-specialty tier, which frequently have cost sharing as much as 50 percent coinsurance. Additionally, many specialty tier-eligible Part D drugs, particularly biological products, often do not have viable alternatives on lower-cost tiers. Our proposal to codify a maximum allowable cost sharing for the specialty tier equal to the cost sharing for the Defined Standard benefit plus the cost of any deductible would ensure Part D enrollees still pay no more than the Defined Standard cost sharing for high-cost drugs placed on a specialty tier.

Although CMS is proposing to allow Part D sponsors to have up to two specialty tiers, CMS notes that the currently available tier model structures already allow Part D sponsors to negotiate rebates and distinguish their preferred high-cost Part D drugs by placing them on the preferred brand tier as opposed to the specialty tier, and placing less preferred agents on the specialty tier. Such distinction could potentially drive the same rebates as two specialty tiers; however, Part D sponsors have told CMS they are reluctant to take such an approach because of the availability of tiering exceptions for the non-specialty tiers, which could increase costs in lower, non-specialty tiers in order to achieve actuarial equivalence. We believe this concern is addressed by our proposal (discussed previously) to permit Part D sponsors to exempt Part D drugs on either or both specialty tiers from exceptions to lower, non-specialty tiers.

Additionally, while CMS is sensitive and trying to be responsive to the volatility of the specialty drug market by proposing to allow Part D sponsors to have up to two specialty tiers, CMS remains concerned about whether this proposal will actually achieve the potential benefits to the Part D program and Part D enrollees asserted by stakeholders in support of two specialty tiers. As discussed previously, those stakeholders contend that permitting two specialty tiers will reduce Part D enrollee cost sharing for specialty Part D drugs. However, this would be true only for Part D drugs on the lower cost-sharing, preferred specialty tier, and only if the lower cost-sharing, preferred specialty tier cost sharing were set lower than 25/33 percent.

When requesting a second specialty tier, some Part D sponsors and PBMs have told CMS they would need to charge more than 25/33 percent for the higher cost-sharing specialty tier. However, if CMS were to permit Part D sponsors to charge more than 25/33 percent for the higher cost-sharing, specialty tier, the cost sharing for drugs in the higher cost-sharing, specialty tier would likely be higher than if there were only one specialty tier. We appreciate that permitting Part D sponsors to increase cost sharing over current limits might lead to negotiations for better rebates, which could result in savings to Part D enrollees offered through, for instance, lower costs on some Part D drugs in the preferred

specialty tier or lower premiums. However, in the absence of evidence to the contrary, it appears to us that if we were to permit Part D sponsors to charge higher percentages than is currently the case, Part D enrollees who need Part D drugs on the higher cost-sharing specialty tier will pay more, and possibly significantly more, than they currently do for those drugs given that specialty tiers by definition offer high-cost drugs, unless they happen to be taking those Part D drugs whose costs are lowered due to better rebates. In other words, we remain concerned about Part D enrollee protections and do not want improved rebates on some Part D drugs to come at the expense of those Part D enrollees who could already be paying, as proposed, as much as a 33 percent coinsurance on the highest-costing drugs. Moreover, because Part D enrollees who use high-cost Part D drugs progress quickly through the benefit, some Part D enrollees' entry into the catastrophic phase of the benefit may be advanced faster if the higher cost-sharing, specialty tier were to have a maximum allowable cost sharing that is higher than 25/33 percent. Therefore, it is unclear to CMS, in the aggregate, how much a second specialty tier would save the government if the second specialty tier was allowed to have a higher cost sharing than the current 25/33 percent.

In addition, while a second specialty tier might improve Part D sponsors' ability to negotiate better rebates, CMS also has concerns regarding actuarial equivalence and discriminatory plan design with a second, higher cost-sharing, specialty tier with cost sharing higher than the 25/33 percent that is currently permitted. If CMS were to allow a maximum allowable cost sharing for the higher cost-sharing, specialty tier above the 25/33 percent that is currently permitted, Part D enrollees whose Part D drugs are placed on the higher cost-sharing, specialty tier could see their out-of-pocket (OOP) costs increase above the Defined Standard cost-sharing amount, yet still be exempt from tiering exceptions. CMS is concerned that the disproportionate impact on Part D enrollees who take Part D drugs on the higher cost-sharing, specialty tier runs a greater risk of discriminatory plan design. Additionally, while it is generally allowable for plans to use tier placement to steer Part D enrollees toward preferred agents, CMS would have to develop additional formulary checks to prevent discrimination against those Part D enrollees who require Part D drugs on the higher cost-sharing, specialty tier, and those additional formulary checks would limit the ability of plans to negotiate for tier placement between the two specialty tiers.

We propose to set a maximum allowable cost sharing for a single specialty tier or, in the case of a plan with two specialty tiers, the higher cost-sharing, specialty tier as follows: (1) For plans with the full deductible provided for in the Defined Standard benefit, 25 percent coinsurance; (2) for plans with no deductible, 33 percent coinsurance; and (3) for plans with a deductible that is greater than $0 and less than the deductible provided for in the Defined Standard benefit, a coinsurance percentage that is determined by subtracting the plan's deductible from 33 percent of the initial coverage limit (ICL) under section 1860D–2(b)(3) of the Act, dividing the difference by the difference between the ICL and the plan's deductible, and rounding to the nearest one percent. We propose to require that a plan's second specialty tier, if any, must have a maximum allowable cost sharing that is less than the maximum allowable cost sharing of the higher cost-sharing, specialty tier. For example, if a Part D sponsor establishes a cost sharing of 25 percent on its higher-cost sharing specialty tier, the Part D sponsor would need to set the cost sharing for the preferred specialty tier at any amount lower than 25 percent. Similarly, if a Part D sponsor establishes a cost sharing of 33 percent on its higher specialty tier (permitted if the plan has no deductible, as discussed previously), the Part D sponsor would need to set the cost sharing for the preferred specialty tier at any amount lower than 33 percent. To encourage the flexibility and with the belief that we might not be able to anticipate every variation Part D sponsors might plan, we are not proposing to require a minimum difference between the cost-sharing levels of the higher cost-sharing, specialty tier and a lower cost-sharing, preferred specialty tier that would apply to Part D sponsors choosing to provide two specialty tiers. As we have generally seen, for example, in relation to our policy recommending a threshold of $20 for the generic tier and ''less than $20'' for the preferred generic tier,[49] we believe it would be unlikely that Part D sponsors would take the trouble to create two different tiers and then establish an inconsequential differential. That said, we would, of course, reexamine this policy if we were to finalize this provision and thereafter find that not requiring a minimum difference between the cost-sharing levels of the two specialty tiers was creating problems. And we solicit comment as to whether to set a numeric or other differential in cost sharing between a specialty tier and any preferred specialty tier, including suggestions on requiring a minimum difference between the cost-sharing levels of the two specialty tiers that can provide maximum flexibility and anticipate varied approaches that Part D sponsors might take. Lastly, nothing in our proposal would prohibit Part D sponsors from offering less than the maximum allowable cost sharing on either tier as long as the preferred specialty tier has lower cost sharing than the higher cost-sharing, specialty tier.

As mentioned previously, CMS has ongoing concerns that offering a lower cost-sharing, preferred specialty tier below the current 25/33 percent maximum could, in theory, lead to increased costs in lower, non-specialty tiers in order to achieve actuarial equivalence. However, because these increases in costs would be spread across the overall plan design, we believe the overall impact on Part D enrollees, would be less impactful than the increase on individual Part D enrollee cost sharing were we to permit a maximum allowable cost sharing for the specialty tier above what is currently permitted (25/33 percent). Although CMS is concerned about offsetting increases to lower, non-specialty tiers, the 25/33 percent maximum allowable cost sharing that we are proposing is based upon the Defined Standard benefit cost sharing and therefore would provide is an important Part D enrollee protection to prevent discriminatory benefit structures. Consequently, CMS believes this approach would strike the appropriate balance between Part D sponsor flexibility and Part D enrollee access. CMS would monitor bids to assess the impact of this proposed policy.

In summary, CMS proposes to add a new paragraph at § 423.104(d)(2)(iv)(D) to specify that a Part D plan may maintain up to two specialty tiers. Further, CMS proposes to set a maximum allowable cost sharing for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost-sharing, specialty tier by adding paragraphs (d)(2)(iv)(D)(*1*), (*2*), and (*3*) which provide: (1) 25 Percent coinsurance for plans with the full deductible provided under the Defined Standard benefit; (2) 33 percent

[49] See page 212 of the Final 2020 Call Letter, available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

coinsurance for plans with no deductible; and (3) for plans with a deductible that is greater than $0 and less than the deductible provided under the Defined Standard benefit, a coinsurance percentage that is between 25 and 33 percent, determined by subtracting the plan's deductible from 33 percent of the initial coverage limit (ICL), dividing this difference by the difference between the ICL and the plan's deductible, then rounding to the nearest one percent.

We solicit comment on this approach. CMS is also interested in and seeks comments on plan benefit designs with two specialty tiers if we were to permit the higher cost-sharing, specialty tier to have a higher coinsurance than what we have proposed. Specifically, CMS is interested in comments that discuss whether permitting a coinsurance higher than 25/33 percent would be discriminatory.

Additionally, we note that the deductible applies to all tiers, and is not limited to, nor borne solely by, Part D enrollees taking Part D drugs on the specialty tier. Therefore, it is unclear that we should continue to differentiate the specialty tier from the other tiers on the basis of the deductible. Accordingly, we are also considering adopting a maximum allowable cost sharing of 25 percent for any specialty tier, regardless of whether the plan has a deductible. We solicit comment on alternative approaches of using a maximum allowable cost sharing of 25 percent coinsurance regardless of whether there is a deductible.

To summarize, we are proposing to add a new paragraph at § 423.104(d)(2)(iv)(D) to: (1) Specify that a Part D plan may maintain up to two specialty tiers; and (2) set a maximum allowable cost sharing of 25/33 percent for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost-sharing specialty tier. We are also proposing to allow Part D sponsors to set the cost sharing for the preferred specialty tier at any amount lower than that of the higher cost-sharing, specialty tier. Additionally, we solicit comment on actuarial equivalence and the potential for discriminatory effects plan designs with two specialty tiers if we were to permit: (1) The higher cost-sharing, specialty tier to have a higher coinsurance than the 25/33 percent maximum allowable cost sharing we have proposed; or (2) a maximum allowable cost sharing of 25 percent without regard to deductible. Finally, we also solicit comment as to whether to set a numeric or other differential in cost sharing between a specialty tier and any preferred specialty tier.

5. Tier Composition and Two Specialty Tiers

A few commenters on the Draft 2020 Call Letter suggested that we should create a lower cost specialty tier for generic drugs and biosimilar biological products, and that such a tier should be limited to only such products. We decline to propose such a policy. First, we wish to provide maximum flexibility to Part D sponsors that might find, for instance, that a brand-name Part D drug costs less with a rebate than a generic equivalent or corresponding biosimilar (or interchangeable, when available) biological product. Moreover, generic drugs and biosimilar (or interchangeable, when available) biological products that meet the specialty-tier cost threshold may not always be the lowest-priced product. Second, nothing in our proposal would prohibit Part D sponsors from setting up such parameters should they choose (provided they meet all other requirements, including the proposed maximum allowable cost sharing). Therefore, in order to provide more flexibility for plans to generate potential savings through benefit design and manufacturer negotiations, CMS is not proposing to prescribe which Part D drugs may go on either specialty tier. However, such placement will be subject to the requirements of the CMS formulary review and approval process under § 423.120(b)(2). Additionally, consistent with our current policy, CMS will continue to evaluate formulary change requests involving biosimilar (or interchangeable, when available) biological products on the specialty tiers on a case-by-case basis to ensure they continue to meet the requirements of the CMS formulary review and approval process. (See § 423.120(b)(5).)

CMS solicits comment on whether Part D sponsors should restrict the lower cost-sharing, preferred specialty tier to only generic drugs and biosimilar (or interchangeable, when available) biological products while also placing them along with any other Part D drugs meeting the specialty-tier cost threshold on the higher cost-sharing specialty tier. In other words, either brand or generic drugs and biosimilar (or interchangeable, when available) biological products would be placed on the higher cost-sharing specialty tier, but only generic drugs and biosimilar (or interchangeable, when available) biological products would be placed on the preferred specialty tier. CMS is particularly interested in comments that discuss what impact such a policy would have on non-specialty tiers.

6. Codifying the Specialty-Tier Cost Threshold Methodology

To effectuate the specialty tier, it was necessary to determine which Part D drugs could be placed on a specialty tier. Consequently, we developed a minimum dollar-per-month threshold amount to determine which Part D drugs are eligible, based on relative high cost, for inclusion on the specialty tier. CMS has sought comment on both this methodology used to establish the specialty-tier cost threshold and the resultant value of the specialty-tier cost threshold when publishing the annual Draft Call Letter. Most recently, commenters on the Draft 2020 Call Letter were largely supportive of having a methodology in place to annually evaluate and adjust the specialty-tier cost threshold, as appropriate. While some commenters wanted to maintain the current level (and others wanted to eliminate the specialty tier or reduce its cost sharing), there was broad support to regularly increase the specialty-tier cost threshold. Some comments asked for annual increases, while others wanted us to tie increases to the specialty-tier cost threshold to drug inflation, or benefit parameters. As we will detail later in this discussion, we are proposing to codify, with some modifications, the same outlier PDE analysis we have historically used. Our proposed annual methodology would account for rising drug costs, as well as any potential changes in utilization. By identifying the top one percent of 30-day equivalent PDEs, our proposal aims to create a specialty-tier cost threshold that is representative of outlier claims for the highest-cost drugs. By using PDEs, the proposed analysis would also reflect the fact that the numbers of Part D enrollees filling prescriptions for high-cost drugs as a percentage of all drug claims may vary from year to year. Given the general support for regular increases in the specialty-tier cost threshold, we propose to make adjustments to the specialty-tier cost threshold based on a specific methodology, as discussed later in this section.

Beginning in 2007, CMS established the specialty-tier cost threshold at $500 per month [50] based on identifying outlier claims (that is, the top one percent of claims having the highest negotiated prices as reported on the PDE, adjusted, as described in this

[50] *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/CY07FormularyGuidance.pdf.*

section of this proposed rule, for 30-day equivalent supplies) and increased the threshold to $600 beginning in contract year 2008. The specialty-tier cost threshold remained at $600 per month from contract years 2008 through 2016.[51] [52] In the 2016 analysis for contract year 2017 (using contract year 2015 PDE data), the number of claims for 30 day-equivalent supplies with negotiated prices meeting the existing $600 per month cost threshold exceeded one percent. This, coupled with the significant increase in the cost of Part D drugs since the last adjustment (in 2008), supported an increase in the specialty-tier cost threshold for contract year 2017. To adjust the specialty-tier cost threshold, CMS applied the annual percentage increase used in the Part D benefit parameter updates (that is, 11.75 percent for contract year 2017) to the $600 threshold. This increase in the specialty-tier cost threshold (that is, $70.50), rounded to the nearest $10 increment (that is, $70), was sufficient to reestablish the one percent outlier threshold for PDEs having negotiated prices for 30-day equivalent supplies greater than the threshold. Since contract year 2017, the specialty-tier cost threshold has been $670 per month.

In our April 2018 final rule, we defined specialty tier in regulation at § 423.560 to mean a formulary cost-sharing tier dedicated to very high-cost Part D drugs and biological products that exceed a cost threshold established by the Secretary (83 FR 16509). To improve transparency, we propose to codify current methodologies for calculations relative to the specialty tier, with some changes. As noted previously, it was necessary to establish the composition of a specialty tier in order to effectuate specialty tier exceptions and anti-discrimination policies. Under § 423.560, only very high-cost drugs and biological products that meet or exceed a cost threshold established by the Secretary may be placed on a plan's specialty tier (for example, a negotiated price of or exceeding $670 per month for coverage year 2020). Current guidance at section 30.2.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual describes these high-cost drugs and biological products as those having Part D sponsor-negotiated prices that exceed a dollar-per-month amount established by CMS in the annual Call Letter, which has noted the historical use of a threshold under which approximately 99 percent of monthly PDEs adjusted for 30-day equivalent supplies have been below the specialty-tier cost threshold.

In setting the specialty-tier cost threshold, CMS has historically analyzed prescription drug event (PDE) data for the plan year that ended 12 months before the applicable plan year (for example, CMS used contract year 2017 PDE data to determine the cost threshold for contract year 2019). First, CMS has calculated the number of 30-day equivalent supplies reported on each PDE. We have considered a 30-day equivalent supply to be any days' supply, as reported on each PDE, of less than or equal to 34 days. Thus, a PDE with a 34-days' supply has been considered one 30-day equivalent supply. (This reflects the fact that a full supply of medication for a Part D enrollee could equal less than a month's supply, or reflect manufacturer packaging. For instance, we did not want to triple the cost of a 10-day course of antibiotics to determine the 30-day equivalent supply because that would overstate the Part D enrollee's cost for the full prescription). If the days' supply on the PDE is greater than 34, the 30-day equivalent supply is equal to the PDE's days' supply divided by 30. Thus, for example, a PDE with a 90-day supply has been considered as three 30-day equivalent supplies. Similarly, a PDE with a drug that has been dispensed in a package containing a 45-days' supply has been considered as 1.5 30-day equivalent supplies. This includes long-acting drugs, including, but not limited to long-acting injections. For example, a single injection that is considered to be a 90-days' supply has been considered as three 30-day equivalent supplies.

After determining the number of 30-day equivalent supplies for each PDE, we have calculated the 30-day equivalent negotiated price for the PDE by dividing the PDE's negotiated price by the number of 30-day equivalent supplies reflected on the PDE. Thus, for example, if the PDE is for a 90-days' supply and has a negotiated price of $810, that PDE contains three 30-day equivalent supplies, and the 30-day equivalent negotiated price is $270.

Next, taking into consideration the 30-day equivalent negotiated prices for all Part D drugs for which PDE data are available, CMS has identified the PDEs with 30-day equivalent negotiated prices that reflect the top 1 percent of 30 day-equivalent negotiated prices, and has maintained the specialty-tier cost threshold at an amount that corresponds to the lowest 30-day equivalent negotiated price that is within the top one percent of all 30-day equivalent negotiated prices.

We note that this process may result in dose specificity of eligibility for placement on the specialty tier, such that one strength of a Part D drug may be eligible but another strength may not. For example, suppose that Part D drug X is available as tablets in strengths of 10mg, 20mg, and 30mg taken once daily with 30-day equivalent negotiated prices of $300, $600, and $900, respectively. The 30mg tablets, because their 30-day equivalent negotiated price exceeds the specialty-tier cost threshold, are eligible for placement on the specialty tier, but the 10mg and 20mg tablets are not, because their 30-day equivalent negotiated prices do not exceed the specialty-tier cost threshold.

We believe our existing policy to set the specialty-tier cost threshold such that only the top one percent of 30-day equivalent negotiated prices would exceed it is consistent with the purpose of the specialty tier—that is, that only the highest-cost Part D drugs are eligible for placement on the specialty tier. For this reason, we propose to codify a similar process to adjust and rank PDE data as the basis for determining the specialty-tier cost threshold, as described in this section of this proposed rule. Specifically, instead of 30-day equivalent negotiated prices, we propose to determine the 30-day equivalent ingredient cost to set the specialty tier-cost threshold in the same manner as we have historically done, as described previously in this section.

In addition, to maintain stability in the specialty-tier cost threshold, we propose to set the specialty-tier cost threshold for contract year 2021 to reflect the top 1 percent of 30-day equivalent ingredient costs, at an amount that corresponds to the lowest 30-day equivalent ingredient cost that is within the top 1 percent of all 30-day equivalent ingredient costs. We also propose to undertake an analysis of 30-day equivalent ingredient costs annually, and to increase the specialty-tier cost threshold for a plan year only if CMS determines that no less than a ten percent increase in the specialty-tier cost threshold, before rounding to the nearest $10 increment, is needed to reestablish the specialty-tier cost threshold that reflects the top one percent of 30-day equivalent ingredient costs.

As a hypothetical example, suppose that, in 2020, when analyzing contract year 2019 PDE data for contract year 2021, CMS finds that more than one percent of PDEs have 30-day equivalent ingredient costs that exceed the contract year 2020 specialty-tier cost threshold of

[51] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2017.pdf.*

[52] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf.*

$670. Further, suppose that CMS finds that one percent of the PDEs have 30-day equivalent ingredient costs that exceed $685. This $15 difference represents a 2.24 percent increase over the $670 specialty-tier cost threshold. Under our proposed methodology, we would not increase the specialty-tier cost threshold for contract year 2021.

However, if we suppose that, instead of $685, CMS finds that one percent of the PDEs have 30-day equivalent ingredient costs that exceed $753, then in this scenario, the $83 change represents a 12.39 percent increase over the $670 specialty-tier cost threshold. Under our proposed methodology, because this would be a change of more than 10 percent, we would set the specialty-tier cost threshold for contract year 2021 at $750 which is the nearest $10 increment to $753.

We solicit comment on this proposal. Because CMS notes that rounding down, as in the previous example, would technically cause the new specialty-tier cost threshold to account for very slightly more than one percent of 30 day-equivalent ingredient costs, we are also considering the alternative that CMS would always round up to the next $10 increment. Using the previous example, CMS would have set the threshold for contract year 2021 at $760 instead of $750. This alternative would: (a) Better ensure that the new specialty-tier cost threshold actually reflects the top one percent of claims adjusted for 30-day equivalent supplies, and (b) provide more stability, to the specialty-tier cost threshold, that is, it will theoretically not need to be changed as frequently, because rounding down will always result in a specialty-tier cost threshold that would include more than the top one percent of 30-day equivalent ingredient costs. We do not expect that this alternative would significantly impact the number of Part D drugs that would meet our proposed specialty-tier cost threshold. We solicit comment on this alternative approach to rounding and could finalize an amended version of our proposed language at § 423.104(d)(2)(B) to reflect such alternative. We propose to annually determine whether the adjustment would be triggered using the proposed methodology, and if it is, we would apply the proposed methodology to determine the new specialty-tier cost threshold, which we would announce via an HPMS memorandum or a comparable guidance document. Finally, we propose for contract year 2021 that we would apply our proposed methodology to the contract year 2020 specialty-tier cost threshold of $670, and if a change to the methodology based on comments received on this proposed rule would result in a change to that threshold, we will announce the new specialty-tier cost threshold in the final rule.

CMS has concerns regarding the use of negotiated prices of drugs, as the term is currently defined in § 423.100, in the determination of the specialty-tier cost threshold, because the negotiated prices include all pharmacy payment adjustments except those contingent amounts that cannot reasonably be determined at the point-of-sale. For this reason, negotiated prices typically do not reflect any performance-based pharmacy price concessions that lower the price a Part D sponsor ultimately pays for a drug. Negotiated prices in the PDE record are composed of ingredient cost, administration fee (when applicable), dispensing fee, and sales tax (when applicable). Administration fees, dispensing fees, and sales tax are highly variable. Therefore, because the ingredient cost has fewer variables than the negotiated price, the ingredient cost represents the most transparent, least complex, and most predictable of all the components of negotiated price upon which to base the determination of the specialty-tier cost threshold. Consequently, as noted previously, we propose to use the ingredient costs associated with 30-day equivalent supplies when we determine the specialty-tier cost threshold according to the methodology proposed earlier in this preamble. We do not expect that this change would significantly affect the number of Part D drugs meeting the specialty-tier cost threshold because the ingredient cost generally accounts for most of the negotiated price; however we are proposing this change to use the ingredient cost in order to ensure that we are using the most predictable of all the components of the negotiated price upon which to base the specialty- tier cost threshold.

Using the methodology proposed in this proposed rule and contract year 2019 PDE data that CMS has to date, the specialty-tier cost threshold for contract year 2021 would be $780 as a 30-day equivalent ingredient cost. To determine this proposed threshold, we analyzed 2.2 billion PDEs, and determined the lowest 30-day equivalent ingredient cost that is within the top one percent of all 30-day equivalent ingredient costs to be $780, which did not require rounding. Therefore, we are proposing to increase the specialty-tier cost threshold to $780 (as a 30-day equivalent *ingredient cost*) for contract year 2021 from the previous $670 (as a 30-day equivalent *negotiated price*). While this change will impact the specific dollar threshold amount for specialty-tier eligibility, the specialty-tier cost threshold still accounts for the top 1 percent of all claims, as adjusted for 30-day equivalent supplies. Due to the increased costs of prescription drugs since the previous $670 specialty-tier cost threshold was set several years ago, the top 1 percent of all claims, as adjusted for 30-day equivalent supplies, cost more, on average. Moreover, we estimate that the change from using negotiated price to using ingredient cost only will result in fewer than 20 drugs not meeting the $780 30-day equivalent ingredient cost specialty-tier cost threshold that would have if we continued to use the 30-day equivalent negotiated price.

Additionally, consistent with current guidance in section 30.2.4 in Chapter 6 of the Medicare Prescription Drug Benefit Manual, CMS considers claims history in reviewing the placement of Part D drugs on Part D sponsors' specialty tiers. Consequently, CMS proposes to codify current guidance that a Part D drug will be eligible for placement on a specialty tier if the majority of a Part D sponsor's claims for that Part D drug, when adjusted for 30-day equivalent supplies, exceed the specialty-tier cost threshold. However, for Part D drugs newly approved by the Food and Drug Administration (FDA) for which Part D sponsors would have little or no claims data because such drugs have only recently become available on the market, we propose to permit Part D sponsors to estimate the 30-day equivalent ingredient cost portion of their negotiated prices based on the maximum dose specified in the FDA-approved labeling and taking into account dose optimization, when applicable for products that are available in multiple strengths. If, based on their estimated 30-day equivalent ingredient cost, the newly FDA-approved Part D drug is anticipated to exceed the specialty-tier cost threshold most of the time (that is, more than 50 percent of the time), we would allow Part D sponsors to place such drug on a specialty tier. Finally, such placement would be subject to CMS review and approval as part of our formulary review and approval process.

CMS proposes to add paragraphs (d)(2)(iv)(A), (B), and (C) to § 423.104 and to cross reference this section in our proposed revised definition of specialty tiers, which we are proposing to move to § 423.104, as described later in this section. Specifically, we propose in paragraph (d)(2)(iv)(A) to described in paragraphs (d)(2)(iv)(A)(*1*) through (*4*) the manner by which CMS sets the specialty-tier cost threshold, and further, to describe in paragraph

(d)(2)(iv)(A)(*5*) a Part D drug's eligibility for placement on the specialty tier. We propose that paragraph (d)(2)(iv)(A)(*1*) would specify that CMS uses PDE data, and further, uses the ingredient cost reflected on the PDE to determine the ingredient costs in dollars for 30-day equivalent supplies of drugs. We propose that paragraph (d)(2)(iv)(A)(*2*) would specify how CMS determines 30-day equivalent supplies from PDE data, such that if the days' supply reported on a PDE is less than or equal to 34, the number of 30-day equivalent supplies equals one, and if the days' supply reported on a PDE is greater than 34, the number of 30-day equivalent supplies is equal to the number of days' supply reported on the PDE divided by 30. We propose that paragraph (d)(2)(iv)(A)(*3*) would specify that CMS then determines the amount that equals the lowest 30-day equivalent ingredient cost that is within the top 1 percent of all 30-day equivalent ingredient costs reflected in the PDE data. Further, proposed paragraph (d)(2)(iv)(A)(*4*) would specify that, except as provided in proposed paragraph (B), the amount determined in paragraph (d)(2)(iv)(A)(*3*) is the specialty-tier cost threshold for the plan year. Proposed paragraph (d)(2)(iv)(A)(*5*) would specify that, except for newly FDA-approved Part D drugs only recently available on the market for which Part D sponsors would have little or no claims data, CMS will approve the placement of a Part D drug on a specialty tiers when that Part D sponsor's claims data from the plan year that ended 12 months prior to the applicable plan year demonstrate that greater than 50 percent of the Part D sponsor's PDEs for a given Part D drug, when adjusted for 30-day equivalent supplies, have ingredient costs for 30-day equivalent supplies that exceed the specialty-tier cost threshold.

We propose in paragraph (d)(2)(iv)(B) to describe the methodology CMS will use to increase the specialty-tier cost threshold. Specifically, we propose to increase the specialty-tier cost threshold for a plan year only if the amount determined by proposed paragraph (d)(2)(iv)(A)(*3*) for a plan year is at least ten percent above the specialty-tier cost threshold for the prior plan year. CMS proposes that if an increase is made, CMS would round the amount determined in proposed paragraph (d)(2)(iv)(A)(*3*) to the nearest $10. That amount would be the specialty-tier cost threshold for the applicable plan year.

Finally, CMS proposes paragraph (d)(2)(iv)(C) to specify that the determination of the specialty-tier cost threshold for a plan year is based on PDE data from the plan year that ended 12 months prior to the beginning of the applicable plan year.

As mentioned previously, to align the definition of specialty tier with our proposal to allow Part D sponsors to have up to two specialty tiers, CMS first proposes to move the definition of specialty tier from § 423.560 to appear in § 423.104(d)(2)(iv) as part of a proposed new section on specialty tiers that also includes the methodology for determining the specialty tier cost-thresholds and maximum allowable cost sharing. (We also propose to revise § 423.560 and § 423.578(a)(6)(iii) to cross reference the placement of that definition in § 423.104(d)(2)(iv).) Additionally, CMS proposes to amend the definition of specialty tier to reflect our proposal to allow Part D sponsors to have up to two specialty tiers. With respect to the phrase ''and biological products,'' for the reasons discussed in the previous section of this preamble, (specifically, that biological products are already are included in the definition of a Part D drug at § 423.100), CMS is also proposing a technical change to the definition of specialty tier to remove the phrase ''and biological products.'' Therefore, CMS proposes to define specialty tier at § 423.104(d)(2)(iv) to mean a formulary cost-sharing tier dedicated to high-cost Part D drugs with ingredient costs for a 30-day equivalent supply (as described in § 423.104(d)(2)(iv)(A)(*2*)) that are greater than the specialty-tier cost threshold specified in § 423.104(d)(2)(iv)(A).

To summarize, we are proposing to: (1) Amend the definition of specialty tier at § 423.560 and move it to § 423.104(d)(2)(iv); (2) amend § 423.578(a)(6)(iii) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv); (3) add new paragraph (d)(2)(iv)(A) which describes, in (d)(2)(iv)(A)(*1*) through (*4*), the manner by which CMS sets the specialty-tier cost threshold, and in (d)(2)(iv)(A)(*5*), a Part D drug's eligibility for placement on the specialty tier; (4) add new paragraph (d)(2)(iv)(B), which describes the methodology CMS will use to increase the specialty-tier cost threshold; and (5) add new paragraph (d)(2)(iv)(C), which specifies that the determination of the specialty-tier cost threshold for a plan year is based on PDE data from the plan year that ended 12 months prior to the beginning of the applicable plan year. We solicit comment on specifying at the proposed new § 423.104(d)(2)(iv)(B) that we would round *up* to the nearest $10 increment.

G. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

Section 101 of the MMA requires the adoption of Part D E-Prescribing (eRx) standards. Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations offering Medicare Advantage Prescription Drug Plans (MA–PD) are required to establish electronic prescription drug programs that comply with the e-prescribing standards that are adopted under this authority.

Prescribers and dispensers who electronically transmit and receive prescription and certain other information for Part D-covered drugs prescribed for Medicare Part D eligible individuals, directly or through an intermediary, are required to comply with any applicable standards that are in effect. For a further discussion of the statutory basis for this proposed rule and the statutory requirements at section 1860D–4(e) of the Act, please refer to section I. of the February 4, 2005, Medicare Program; E-Prescribing and the Prescription Drug Program Proposed Rule (70 FR 6256).

In accordance with our regulations at § 423.160(b)(1), (2), and (5), CMS' Part D eRx program requires that Part D sponsors support the use of the adopted standards when electronically conveying prescription and formulary and benefit information regarding Part D-covered drugs prescribed to Part D-eligible individuals between plans, prescribers, and dispensers.

We utilized several rounds of rulemaking to update the Part D e-prescribing program. Most recently, in the May 2019 Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses Final Rule (84 FR 23832) (hereinafter referred to as the May 2019 final rule), we required that Part D plans support a prescriber electronic real-time benefit tool capable of integrating with at least one e-prescribing or electronic health record (EHR) system. The prescriber RTBT must provide its enrollees with complete, accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives and utilization management requirements). This ''prescriber RTBT'' electronic transaction requirement will become effective January 1, 2021, and is expected to enhance medication adherence and lower overall drug costs by providing Part D prescribers information in real time when lower-cost alternative drugs are available.

The SCRIPT and the NCPDP Formulary and Benefits standards have already become critical components of the Part D program, and we believe the recently finalized prescriber RTBT requirement at § 423.160(b)(7) will do the same by enhancing the electronic communication of prescription-related information between plans and prescribers under the Part D benefit program. While these requirements will empower prescribers, we also believe it is important to empower patients with information like that which will be included in the prescriber RTBT and give them the ability to access this information either at their computer or using a mobile device. We now propose to adopt at § 423.128(d) a requirement that Part D sponsors implement a beneficiary RTBT that would allow enrollees to view accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information, effective January 1, 2022, so as to allow both prescriber and patient to consider potential cost differences when choosing a medication that best meets the patient's medical and financial needs. Each system response value would be required to present real-time values for the patient's cost-sharing information and clinically appropriate formulary alternatives, where appropriate. This requirement would include the formulary status of clinically appropriate formulary alternatives, including any utilization management requirements, such as step therapy, quantity limits, and prior authorization, applicable to each alternative medication. We're also proposing to add § 423.128(d)(1)(vi) to require that plans make this information available to enrollees via their customer service call center. The goal of this requirement is help ensure that the beneficiary RTBT information is available to enrollees without computer or smartphone access.

We believe that January 1, 2022 is an appropriate deadline for this proposal, since it would give plans adequate time to implement the proposal while still helping ensure that enrollees have access to this information in a timely manner. We welcome comments on this proposal, including the feasibility for plans to meet the proposed January 1, 2022 deadline or whether this proposal should be finalized effective January 1, 2021 in order to align with the prescriber RTBT effective date.

We also welcome comments on the need for the beneficiary RTBT when Part D plans will be required to support the prescriber RTBT by January 1, 2021. For instance, we would like to understand the beneficiary interest in such a tool compared to provider interest. We also would like to understand whether a beneficiary RTBT is a less complicated, therefore more likely utilized tool, than a prescriber RTBT.

As we stated in our April 16, 2018 final rule adopting version 2017071 of the SCRIPT standard for various Part D e-prescribing transactions (see 83 FR 16440), we believe that patient-specific coverage information at the point of prescribing would enable the prescriber and patient to collaborate in selecting a medication based on clinical appropriateness, coverage, and cost. In order to fully realize this benefit, however, we believe that it is important to afford the patient direct access to this formulary and benefit information so they need not depend on their prescribers pulling up the information to empower their discussions with those prescribers as to medication options.

Section 1860D–12(b)(3)(D) of the Act authorizes additional contract terms not inconsistent with the Part D statute. Under this authority, we are proposing to require Part D sponsors to offer a patient RTBT because we believe that it is appropriate to require that the formulary and benefit information be provided to enrollees in real time. Enrollees should have continuous access to this information, since drug pricing information is so dynamic.

Based on our research, we believe that the process that Part D sponsors will have to follow in order to implement a prescriber RTBT would establish a foundation from which a beneficiary RTBT could be implemented for use by enrollees, since the required information and information culling process is substantially similar. As discussed in our May 2019 final rule, implementation of an effective prescriber RTBT requires that plans review formulary medications to determine which alternatives may exist and whether those alternatives could save the beneficiary money through reduced cost sharing if deemed clinically appropriate by the practitioner. As discussed in our May 2019 final rule, analysis needed when developing the formulary and benefit information necessary to implement prescriber RTBTs would also include cataloging any existing drug-specific utilization requirements such as prior authorization (PA) or step therapy. Specifically, the plan's prescriber RTBT system will require integration with at least one prescriber's e-Prescribing (eRx) system or electronic health record (EHR) to provide complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit information to the prescriber in real time for assessing coverage under the Part D plan (§ 423.160(b)(7)). Such information must include enrollee cost-sharing information, clinically appropriate formulary alternatives, when available, and the formulary status of each drug presented including any utilization management requirements applicable to each alternative drug. Once the Part D sponsor has developed the information necessary to implement the prescriber RTBT, the list of formulary alternatives and utilization requirements could also be used to implement a beneficiary RTBT.

We believe that sharing this kind of formulary and benefit information would allow enrollees to take an active role in their health care decisions, which we believe would yield greater medication adherence. In our May 2019 final rule (see 84 FR 23832), we cited evidence suggesting that reducing medication cost yields benefits in increased patient medication adherence. Evidence indicated that increased medication out-of-pocket costs was associated with adverse non-medication related outcomes such as additional medical costs, office visits, hospitalizations, and other adverse events. Given that patient cost is such a determinant of adherence, allowing the patient greater access to drug cost information, independent of their prescriber, should improve medication adherence. Further, research shows that when patients play an active role in their health care decisions the result is increased patient knowledge, satisfaction, adherence with treatment and improved outcomes.[53] Although not all patients will chose to actively participate in treatment decisions, interactive discussions between patients and physicians are correlated with improved patient satisfaction with their health care provider.[54]

We believe that bringing all of these benefits to Part D enrollees is especially important, in light of the fact that the Medicare population is becoming increasingly comfortable with technology. According to a 2017 Pew Research Center study, some groups of seniors, particularly those who are younger, report ''owning and using various technologies at rates similar to adults under the age of 65''[55] and also characterized ''82 percent of 65- to 69-year-olds as internet users'' and found

[53] See *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1855272/*.

[54] See *https://www.ncbi.nlm.nih.gov/pubmed/11021677/*.

[55] Report is accessible at *https://www.pewinternet.org/2017/05/17/technology-use-among-seniors/*.

that 40 percent of seniors now own smartphones, ''more than double the share that did so in 2013''. As more seniors use computers and smart phones in their daily lives, they may use electronic means to research information about their prescription medications. CMS believes that the Part D program must move to accommodate those enrollees by enhancing the way that digital technologies are used in the Part D e-prescribing context. We are aware that some Part D plans have already created beneficiary portals.

The intent of this proposal is to ensure that enrollees have access to formulary and benefit information while giving plans latitude to determine how to meet this beneficiary need. We encourage Part D sponsors to explore whether a beneficiary RTBT function could be added to existing beneficiary portals with the intent of giving enrollee access to a variety of drug plan services through a single secure portal. Alternatively, if this provision is finalized, Part D plans could also create dedicated beneficiary RTBTs for use on a computer or smart phone or create a new patient portal for this purpose. We propose to allow for either of these solutions.

When developing their solutions, Part D Plans should also be mindful of ensuring their compliance with their current non-discrimination responsibilities and obligations, particularly to individuals who are deaf, hard of hearing, or blind, or who have other sensory or manual impairments.[56] Plans should be mindful of complying with current regulations at 28 CFR 36.303 45 CFR 84, 92.4, and 92.202. In addition, should this proposal be finalized, Part D Plans should ensure that beneficiaries without computer or smart phone access can retrieve the same formulary and benefits information available on the beneficiary RTBT via calling the Plan's call center. We believe that this is important to help guarantee that all Part D enrollees have equal access to the information on the beneficiary RTBT.

Currently, enrollees in Part D can use a number of tools to access prescription drug information for their particular plan, but the tools do not offer the advantages of a beneficiary RTBT. Blue Button 2.0 is an application programming interface that provides traditional Medicare beneficiaries with cost and beneficiary information after those expenses are incurred. By contrast, the beneficiary RTBT would provide the information before the expenses are incurred, so that beneficiaries and prescribers can have meaningful conversations about their medications before choosing the most appropriate medication. The Medicare Plan Finder (MPF) (*https://www.medicare.gov/find-a-plan/questions/home.aspx*) is a web tool that is available to the public. The web tool allows beneficiaries to make informed choices about enrolling in Part D plans by comparing coverage options based on the plans' benefit package (PBP), premium, formulary, pharmacy, and pricing data. Beneficiaries also use the MPF to evaluate their estimated annual out-of-pocket drug costs at the selected pharmacies from those pharmacies available in their area. These tools are powered by the data Part D sponsors submit to CMS and its contractors. In addition, the web tool also shows the plans' Star Ratings, which can be used by beneficiaries to evaluate quality and performance of available plans.

Part D plan enrollees can also access helpful information by viewing plan websites, which contain their current plan formularies, including the drug tiers and any PA requirements. Enrollees can use these tools to predict cost sharing for the medication selected.

Although the aforementioned tools are helpful, neither the MPF nor plan websites identify drug-specific formulary alternatives for enrollees, nor can they provide beneficiary-specific PA information. For example, a plan may have a PA requirement on a drug and that requirement would be listed on the online formulary and in MPF. However, if a PA request for a drug for a particular beneficiary has already been approved and additional PA is not required for that enrollee, he or she could not ascertain that information unless they call the plan. Similarly, as beneficiary costs vary depending upon the benefit phase, the costs included on MPF and plan websites may not accurately reflect beneficiary-specific out-of-pocket costs based on the applicable phase of the benefit phase that the beneficiary is in at that point in time. Although we are proposing that plans can use similar formulary and benefit information to implement both a prescriber and a beneficiary RTBT, we recognize that there would be inherent differences in the way that each real time benefit tool will be used, and each tool raises different concerns. First, the end user of the beneficiary RTBT would be the beneficiary, and since the data would not be passed on from the beneficiary RTBT to another system, we believe that the information released would have to be information that is understandable to the average patient and that can be of use to them in their interactions with their provider, whereas the information from the prescriber RTBT would be information that is understandable to prescribers. Second, there are not any different standards available for a beneficiary tool, since plans can use their own portals or computer applications for the beneficiary RTBT, and a standard is only required when information flows to another system. We invite comment on these issues.

We understand that, generally, most enrollees may not have the clinical background required to accurately discern the clinical appropriateness of the alternatives that would be presented to a prescriber using an RTBT. We realize that there may be occasions where certain drugs, for example certain antibiotics which are ''drugs of last resort'' that are typically reserved for instances in which the patient is found to have certain drug-resistant infections, or instances in which side-effects are such that a given prescription would not typically be selected in the absence of countervailing risks that would justify risking such side-effects, or instances in which there would be interactions with other drugs already used by the beneficiary that would contra-indicate prescribing a given drug. In these and other clinically appropriate instances, we believe it may be appropriate to omit certain drugs from what is presented to the user of a beneficiary RTBT. Furthermore, where there are many potential prescriptions that could be presented to the beneficiary through an RTBT for a given condition, and those drugs fall exclusively in a small number of classes or categories of drugs, it may be appropriate to allow the RTBT to present those classes or categories rather than requiring the listing of every medication for that condition as it may be overly burdensome for Part D sponsors to do otherwise, and confusing for enrollees. Thus, in order to address these and other clinically appropriate scenarios, we propose that Part D sponsors would be permitted to have their Pharmacy and Therapeutics (P & T) committees evaluate whether certain medications should be excluded from the beneficiary RTBT. P & T committees should exclude medications from the beneficiary RTBT if any of the following criteria are met: (1) The only formulary alternatives would have significant negative side effects for most enrollees and the drug would not typically be a practitioner's first choice for treating a given condition due to those side effects, (2) for cases where medications

[56] These responsibilities and obligations include compliance with Title VI of the Civil Rights Act of 1964, sections 504 and 508 of the Rehabilitation Act, the Age Discrimination Act, and section 1557 of the Affordable Care Act.

are considered to be ''drugs of last resort,'' (3) instances in which there would be interactions with other drugs already used by the beneficiary that would contra-indicate prescribing a given drug, or (4) other clinically-appropriate instances.

We propose to allow these exceptions to what should be provided to beneficiary RTBTs, since we believe that it will help ensure that beneficiaries have reasonable access to information about the viable alternatives for treating their conditions which will increase transparency about drug alternatives over what is currently available, while addressing what we believe are reasonable policy concerns about the potential ill-effects of providing unfiltered information to consumers. We note that this would only be appropriate in limited circumstances. In order to provide the most appropriate decision support to beneficiaries, we propose at this time to defer to plans and their medical professionals to choose which medication options should be presented in the beneficiary RTBT, but we would monitor for improper use of this discretion, and would propose changes if this discretion is found to be abused. Alternatives must only be excluded based only on clinical appropriateness, not based on any cost implications to the beneficiary or plan. By contrast, prescriber RTBTs must show all medication alternatives, since prescribers have the ability to discern which medications can appropriately treat the specific issues and what their side effects could be.

Should this proposal be finalized, if plans do not populate the beneficiary RTBT with all options, Part D plans would be required to indicate to the Part D enrollee that not all potential medication options are included and the rationale for why not all options were included. Although we recognize that in some cases information presented through RTBT would thereby differ for beneficiaries and providers, we believe that the provider would be positioned to explain the differences if they are brought to the providers' attention. We propose that the fact that a beneficiary received a curated listing of options would need to be prominently shown in the human-readable output of the technology used by the beneficiary to access the formulary and benefit information, such as on the screen viewed through a patient portal or computer application or the print out generated using such portal or application.

However, we want to clarify that the data that we are proposing to require be provided in the beneficiary RTBT must be patient-specific, clinically appropriate, timely, and accurate, and must be devoid of commercial purposes that would adversely impact the intended functionality of promoting cost-effective beneficiary and prescriber selections of drugs. Such improper commercial purposes would include the presentation of advertising in the beneficiary RTBT, outputs that are intended to promote choices based on the commercial interests of the part D sponsor rather than the beneficiary's best interests, or the promotion of medications or refills based on the rebates that would be received. We also would consider it a best practice, should the proposal be finalized, for beneficiary RTBTs to include cost-sharing amounts for medications if purchased at a pharmacy selected by the beneficiary, provided the pharmacy is in the plan's network. Sponsors would also be allowed to provide cost data for alternative pharmacies in the plan's network. However, due to concerns with enrollees being improperly steered to different pharmacies, we are not proposing to require that beneficiary RTBTs include pharmacy-specific cost sharing information.

In order to support maximum transparency, CMS also encourages plans to show each drug's negotiated price (as defined in § 423.100) in the beneficiary RTBTs in addition to the requirement to reflect the beneficiary's out-of-pocket cost information at the beneficiary's currently chosen pharmacy. Alternatively, if the beneficiary RTBT does not show the negotiated price, we would encourage plans to provide additional cost data comparing the beneficiary and plan cost comparisons for each drug and its alternatives. For example, if Drug A has beneficiary cost sharing of $10 and the plan pays $100, and Drug B also has a beneficiary cost sharing of $10 but the plan only pays $90, the beneficiary RTBT would reflect a difference of $0 for cost sharing and −$10 in comparative plan cost for Drug B. Providing data such as negotiated price or comparative plan costs would provide beneficiaries with a better understanding of the price differences between alternative drugs and could help provide beneficiaries with information on potential clinically appropriate alternatives that could steer a discussion with their clinician and provide the biggest savings to the beneficiary and potentially lower Part D costs overall. Although we encourage the inclusion of the negotiated price and other comparative information in the beneficiary RTBT, we are not proposing to require the inclusion of such information at this time. We are also not proposing this requirement at this time because we don't have research that shows learning the payer's rate will effect beneficiary choice if there is no effect on their payment amount. However, we solicit comment on this proposal.

To summarize, we propose that each Part D sponsor implement a beneficiary real time benefit tool that will allow enrollees to view a plan-defined subset of the information included in the prescriber RTBT, which includes accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including enrollee cost-sharing information, clinically appropriate formulary alternatives, subject to the aforementioned exceptions, and the formulary status of each drug presented including any utilization management requirements applicable to each alternative drug), no later than January 1, 2022. Plans are encouraged, but would not be required, to include the negotiated price. Plans could meet this proposed requirement by using existing or new secure patient portals, or an application or other technology. We seek feedback on this proposal, including if any further limitations should be imposed, what type of information should be included in the beneficiary RTBT, and the value of this tool being in the hands of the beneficiary and the prescriber.

In addition, in order to encourage enrollees to use the beneficiary RTBT, we propose to allow plans to offer rewards and incentives (RI) to their enrollees who use the tool. We propose to define use, for purposes of permitted RI, to mean logging onto either the portal or application or calling the plan's call center to ask for this information, without regard to whether the enrollee engages in a discussion with his or her prescriber or obtains or switches to any medication in response to such use. In other words, we propose that plans who choose to offer RI must offer it to all plan enrollees who use the tool or seek to access this information via phone and must not make RI contingent upon the medical diagnosis or the type of medication a beneficiary is taking, or upon the enrollee switching medications.

In addition, we prohibit any enrollee remuneration under the guise of RI, which includes waivers of copayments and deductible amounts and transfers of items or services for free. We also prohibit plans from offering any cash or monetary donations, under the guise of RI. However, we do allow for the use of

gift cards, as long as they are not cash equivalents and do not encourage enrollees to further patronize the plan or any of the plan's corporate affiliates. CMS considers gift cards to be used like cash, for example, a VISA or Amazon gift card, to be a ''cash equivalent.'' Cash equivalents also may include, for example, instruments convertible to cash or widely accepted on the same basis as cash, such as checks and debit cards. This means that gas cards or restaurant gift cards would be permitted. However, a gift card that can be used for goods or services purchased from the plan would be prohibited, since that could incentivize enrollment in plans that could provide gift cards that enrollees could use at pharmacies or retail stores owned by their plan, rather than at a third-party establishment owned by a different company.

In addition, we seek to minimize risks of violations of the Federal anti-kickback statute and compromising the integrity of the program.

We also propose that the RI be of nominal value, which OIG guidance specifies as no more than $15 per login or $75 in the aggregate annually, in accordance with OIG guidance.[57] We also propose that the member can receive a RI for no more than one login per month. Should this proposal be finalized, this expense would have to be included as an administrative expense in the bids of Part D sponsors. We would prohibit it from being considered a drug cost. We seek comments on these limitations and on how we can ensure that these RIs will not be indirectly provided or funded by pharmaceutical manufacturers. We also seek comments on safeguards to mitigate risks of fraud and abuse with respect to these incentives.

MA–PDs are already permitted to offer rewards and incentives for Part C benefits under our regulation at § 422.134, which permits plans to offer health-driven rewards and incentives that are designed to encourage enrollees to participate in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources. We propose to adopt Part C's ban at § 422.134(b) on discrimination for Part D RI that plans offer to encourage the use of the beneficiary RTBT. We therefore propose to require that if a plan offers RI, it must be available to all of the plan's enrollees that log into the plan's portal or call the plan's call center, regardless of the enrollee's race, national origin, gender, disability, chronic disease, health status, or basis prohibited by any applicable law.

Our statutory authority to allow RI for beneficiary RTBT stems from section 1860D–4(c)(1)(A) of the Act, which requires Part D sponsors to have in place, directly or through appropriate arrangements, a cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate. We believe that an RI program for beneficiary RTBTs could be part of the plan's effective UM program, since they help inform and remind Part D enrollees about their utilization management requirements for their medications and provide them with alternatives that may be more appropriate for enrollees' individual health and budgetary needs. As a result, we believe that this provision would fall under the utilization management provisions of the Act. Previously, CMS has solicited comment from Part D sponsors about whether allowing rewards and incentives in Part D would be beneficial.[58] Specifically, we asked for input on the kinds of RI Program(s) Part D sponsors would propose to offer enrollees, the level of incentives Part D sponsors believe would be necessary to achieve positive outcomes for beneficiaries, such as medication adherence, and how to mitigate any concerns about a sponsor potentially selecting healthier beneficiaries for rewards. Commenters expressed interest in allowing for RI under Part D, and offered a variety of different suggestions about the types of rewards to incent enrollees. However, we did not receive suggestions about how to mitigate concerns about sponsors potentially selecting healthier beneficiaries for rewards.

Over the past several years, plans and vendors have written CMS to express their interest in allowing RI under Part D. In addition, CMS has obtained additional information demonstrating that RI can positively impact beneficiaries' health-related choices by increasing medication adherence and encouraging beneficiaries to choose lower-cost alternative medications.[59] [60] [61] [62] Since the objectives of the beneficiary RTBT so closely align with these goals, we believe that allowing Part D plans to offer RI for beneficiary RTBT usage would further incentivize beneficiaries to use the RTBT, while providing CMS the opportunity to further review the impact of RI under Part D by examining the differences in costs and beneficiary behavior between plans that use RI versus plans that do not. We propose to add this provision to our regulations at § 423.128 by amending paragraph (d) to add paragraphs (a)(4) and (5). Paragraph (a)(4) would address the beneficiary RTBT and paragraph (a)(5) would address the rewards and incentives for use of the beneficiary RTBT. We believe that this proposal fits under § 423.128, since it is consistent with the requirements under that provision to increase transparency to Part D enrollees. We believe that this new tool would enhance the existing disclosures by providing another means for Part D enrollees to access the information.

H. Establishing Pharmacy Performance Measure Reporting Requirements (§ 423.514)

Section 1860D–12(b)(3)(D) of the Act provides broad authority for the Secretary to add terms to the contracts with Part D sponsors, including terms that require the sponsor to provide the Secretary with information as the Secretary may find necessary and appropriate. Pursuant to our statutory authority, we codified these information collection requirements for Part D sponsors in regulation at § 423.514.

Section 423.514(a) requires each Part D sponsor to have a procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, statistics indicating the following: (1) The cost of its operations; (2) the patterns of utilization of its services; (3) the availability, accessibility, and acceptability of its services; (4) information demonstrating it has a fiscally sound operation; and (5) other matters as required by CMS.

[57] *Office of Inspector General Policy Statement Regarding Gifts of Nominal Value To Medicare and Medicaid Beneficiaries*, Office of Inspector General (2016).

[58] See the 2014 Call Letter, available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/Announcement2014.pdf.*

[59] *The Effectiveness of Financial Incentives for Health Behaviour Change: Systematic Review and Meta-Analysis Giles EL, Robalino S, McColl E, Sniehotta FF, Adams J (2014) The Effectiveness of Financial Incentives for Health Behavior Change: Systematic Review and Meta-Analysis.* PLOS ONE 9(3): e90347. *https://doi.org/10.1371/journal.pone.0090347.*

[60] *Personal financial incentives for changing habitual health-related behaviors: A systematic review and meta-analysis.* Mantzari, Eleni, et al. *Preventive medicine* 75 (2015): 75–85.

[61] *Acceptability of financial incentives for health behavior change to public health policymakers: A qualitative study*, Giles, Sniehotta, et al. *BMC Public Health* (2016).

[62] *A Simulation Modeling Framework to Optimize Programs Using Financial Incentives to Motivate Health Behavior Change* Basu, Kiernan *Medical Decision Making* (2016).

We established the Part D reporting requirements to monitor the prescription drug benefit to ensure a safe, consistent and fair experience for beneficiaries purchasing medication through the Part D prescription drug program. These data have successfully enabled us to respond to questions about the Part D program and to identify Part D sponsors that are not operating in an equitable manner in regard to their respective enrollees and not in compliance with specific contractual terms required by the Medicare Part D program. Consistent with § 423.514(a), the reporting requirements program requires Part D sponsors to report a set of performance measures either annually or quarterly providing an element of transparency to the Part D program as many of the performance measures' results are made public. Over time we have added or retired reporting requirements and any corresponding data elements as our needs to evaluate the program evolved. New reporting sections and changes to the data elements are proposed for public comment in the **Federal Register** and approved through the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) process. The current Part D reporting requirements (OMB 0938–0992) may be accessed at: *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.html*.

We propose to amend the regulatory language at § 423.514(a) to establish a requirement for Part D sponsors to disclose to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network pharmacy agreement. Collecting pharmacy performance measures used to determine whether a financial reward or penalty is incurred by a pharmacy after the point-of-sale (POS) will enable CMS at a minimum to better understand the extent to which the measures are applied, whether it be uniformly or specific to pharmacy type. This effort may also explain if there is a pharmacy performance problem, as pharmacy price concessions (financial penalties incurred) after the POS have continued to grow annually. Knowledge of the industry's pharmacy performance measures would also provide transparency to the process and likely confirm or dispel the idea that many of the measures may not provide appropriate metrics across all types of pharmacies. Given the growing use of pharmacy performance measures in determining the final cost of a drug under Part D and the impact of these recoupment practices on the amount a beneficiary pays for a Part D drug at the POS, we believe this information to be essential if there is to be predictable reimbursement for pharmacies and cost sharing for beneficiaries.

Once collected, CMS would publish the list of pharmacy performance measures to increase public transparency. The public would benefit from the release of this information because pharmacy services are expanding, and therefore, it is imperative to measure the care provided. Quality measures can document a pharmacy's contribution to value-based care and incentivize high quality care. We believe collecting this information is the right thing to do for patients and our healthcare system. Standardized pharmacy measures bring value and relevance to patient care and cost management. In addition, this supports collaboration and consensus within the pharmacy industry. Collected data elements would be limited to those necessary to identify and understand each measure and how it is applied by pharmacy type, if applicable and may include:

- Name of the performance measure
- Performance calculation methodology
- Success/failure threshold(s)
- Financial implications of success/failure to achieve threshold(s)
- Pharmacy appeal requirements; and
- Method of payment of collection

We may also consider collecting retrospective information on the number of pharmacies by pharmacy type, if applicable that achieved established success/failure thresholds and average scores or other statistics for each measure. If this proposal is finalized, the actual Part D reporting requirements data elements (consistent with our adopted standard), timeline, and method of submission would then be proposed through the OMB PRA process after publication of the final rule. We normally seek comment on a new information collection and its associated burden through rulemaking, however, we believe the best approach is to have the industry first begin to develop, test and achieve a consensus on the measures themselves, via a measure developer. Then, we would provide an opportunity for the industry to comment on more specific data collection instruments via notices in the **Federal Register**. This encourages collaboration and consensus within the industry and promotes alignment across the pharmacies and plans. We would also have the opportunity to gather initial feedback on the actual data elements in response to this proposal.

We encourage the industry to continue to work together on developing a set of pharmacy performance measures through a consensus process and Part D sponsors to adopt such measures to ensure standardization, transparency and fairness. We also encourage Part D sponsors to use a third party, independent organization that is free of conflict of interest to assess pharmacy performance on such measures (including data aggregation, development of measure thresholds and cut points, and definition of applicable pharmacy types for each measure). We are aware that the Pharmacy Quality Alliance (PQA), a measure developer, hosted a consensus building workshop in early 2019 and hosted an all-member webinar in late August 2019 to share the results of the workshop to build consensus across pharmacy, plan, PBM, and other stakeholders to create a standard set of feasible, valid, and reliable measures that could be used in plan-pharmacy agreements in Medicare Part D. The participants reached consensus on an approach to prioritize the development of measures in the short, medium, and long term. The PQA plans to re-specify certain plan-level measures at the pharmacy-level and to create new pharmacy-level measures. The short term pharmacy-level measure specifications and testing may be complete in early 2020 for the 2021 contract year. We are encouraged by the progress being made by the industry to establish a consensus set of pharmacy performance measures and encourage the industry to keep us apprised of their efforts in this area.

We recommend that pharmacy performance measures established for use in Part D adhere to the following principles. The measures should—

- Improve medication use and outcomes for the beneficiaries served;
- Be specified at the right level of attribution and appropriate level of comparison considering pharmacy type;
- Factor in both pharmacy accountability and drug plan performance goals;
- Have clear specifications and be established prior to the measurement period;
- Be reliable, transparent and fair; and
- Use threshold minimums if appropriate.

In the future, CMS may develop measures to consider for use in the Part D Star Ratings that, for example, assess Part D plan sponsors' uptake of a standard set of pharmacy performance measures or that evaluate the percent of high-performing pharmacies in the sponsors' pharmacy network.

We solicit comment on the principles that Part D pharmacy performance measures should adhere to, including potential burden or hardship of performance measures on small, independent, and/or rural pharmacies, and recommendations for potential Part D Star Ratings metrics related to these measures. Finally, we solicit comment on the data elements, timeline, and method of submission for the reporting of pharmacy performance measures.

I. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)

1. Background

Section 1103 of Title I, Subpart B of the Health Care and Education Reconciliation Act (Pub. L. 111–152) amended section 1857(e) of the Act to add a medical loss ratio (MLR) requirement to Medicare Part C (MA program). An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care rather than for such other items as administrative expenses or profit. Because section 1860D–12(b)(3)(D) of the Act incorporates by reference the requirements of section 1857(e) of the Act, these MLR requirements also apply to the Medicare Part D program. In the May 2013 Medicare MLR final rule, which codified the MLR requirements for Part C MA organizations and Part D sponsors (including organizations offering cost plans that offer the Part D benefit) in the regulations at 42 CFR part 422, subpart X and part 423, subpart X. In the April 2018 final rule (83 FR 16440), we changed certain aspects of the MLR calculation and revised the reporting requirements.

For contracts for 2014 and later, MA organizations and Part D sponsors are required to report their MLRs and are subject to financial and other sanctions for a failure to meet the statutory requirement that they have an MLR of at least 85 percent (see §§ 422.2410 and 423.2410). The statute imposes several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds to CMS, a prohibition on enrolling new members, and ultimately contract termination. The minimum MLR requirement creates incentives for MA organizations and Part D sponsors to reduce administrative costs, such as marketing costs, profits, and other uses of the funds earned by plan sponsors, and helps to ensure that taxpayers and enrolled beneficiaries receive value from Medicare health and drug plans.

This proposed rule sets forth our proposed changes to the incurred claims portion of the MLR numerator for MA contracts. We are also proposing to codify the current definitions of partial, full, and non-credibility and the credibility factors for MA and Part D contracts, and to add a deductible factor for MA MSA contracts.

2. Regulatory Changes to Incurred Claims (§ 422.2420)

Section 422.2420(a) of the regulations sets forth a high-level definition of the MLR as the ratio of the numerator, defined in paragraph (b), to the denominator, defined in paragraph (c). In general, MA costs are in the numerator and revenues are in the denominator. Section 422.2420(b)(1) identifies the three components of the MLR numerator for MA contracts that are not MSA contracts: (1) Incurred claims (as defined in paragraphs (b)(2) through (4)); (2) the amount of the reduction, if any, in the Part B premium for all MA plan enrollees under the contract for the contract year; and (3) expenditures under the contract for activities that improve health care quality, which are described in detail at § 422.2430. For MA MSA contracts, the three components of the MLR numerator are (1) incurred claims (as defined in paragraphs (b)(2) through (4)); (2) expenditures under the contract for activities that improve health care quality; and (3) the amount of the deposit into the Medicare savings account for MSA enrollees. Our proposal is to revise the regulation text regarding the incurred claims portion of the numerator.

Under current § 422.2420(b)(2)(i), incurred claims include direct claims that the MA organization pays to providers (including under capitation contracts) for covered services (described at paragraph (a)(2) of that section) that are provided to all enrollees under the contract. Section 422.2 defines a ''provider'' for purposes of the MA regulations as any individual or entity that is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the state, or to deliver those services if such licensing or certification is required by State law and regulation. Per § 422.2420(a)(2), ''covered services'' are the benefits defined at § 422.100(c): basic benefits, mandatory supplemental benefits, and optional supplemental benefits.

As explained in greater detail in sections II.A. and VI.F. of this proposed rule, CMS is proposing to revise the regulations at § 422.100 to codify subregulatory guidance and statutory changes that have expanded the types of supplemental benefits that MA plans may include in their plan benefit packages (PBPs). The proposed amendment to § 422.100(c)(2) would codify CMS's longstanding interpretation of the statute to require a supplemental benefit to be an item or service (1) that is primarily health related, such that the benefit diagnoses, compensates for physical impairments or acts to ameliorate the functional or psychological impact of injuries or health conditions, or reduces avoidable emergency and healthcare utilization; (2) for which the MA organization incurs a non-zero direct medical cost; and (3) that is not covered by Medicare Parts A, B, or D. In the contract year (CY) 2019 Call Letter, issued on April 2, 2018, CMS announced that we reinterpreted the scope of the ''primarily health related'' supplemental benefit definition. Under this reinterpretation, to be considered ''primarily health related,'' a supplemental benefit must focus directly on an enrollee's health care needs and should be recommended by a licensed medical professional as part of a health care plan, but it need not be directly provided by one. As part of proposed § 422.100(c)(2), to account for the types of supplemental benefits that may be offered under the policy changes addressed in sections II.A. and VI.F. of this proposed rule, CMS is also proposing specific provisions to address permissible supplemental benefits that are not primarily health related and for which the non-zero direct cost incurred must be a non-administrative direct cost (if it is not a medical cost).

In proposed § 422.102(f), we are proposing to codify regulation text implementing amendments made by the BBA of 2018 to section 1852(a)(3) of the Act to expand the types of supplemental benefits that may be offered to chronically ill enrollees, starting in contract year 2020. Under paragraph (D) of section 1852(a)(3) of the Act, as added by the BBA of 2018, MA organizations may provide SSBCI that are not primarily health related to chronically ill enrollees, as long as the item or service has the reasonable expectation to improve or maintain the chronically ill enrollee's health or overall function.

Under § 422.2420(b)(2)(i) of the MA MLR regulations, incurred claims in the MLR numerator include direct claims paid *to providers* for covered services furnished to all enrollees under an MA contract. The amendment to section 1852(a)(3)(D) of the Act has expanded the types of supplemental benefits that can be ''covered services'' under an MA plan. The proposal to implement that change at § 422.102(f) and the continuation of our policy for establishing what it means for a benefit

to be primarily health related both mean that permissible supplemental benefits might include items and services that would not typically be furnished by an individual or entity that is a ''provider'' as defined at § 422.2. A provider, as defined in § 422.2, is an individual or entity engaged in the delivery of health care services and who is licensed or certified by the State to engage in that activity in the State. To ensure that amounts that an MA organization pays for covered services to individuals or entities that are not health care providers are included in incurred claims under current § 422.2420(b)(2)(i), we propose to amend the regulation to remove the specification that incurred claims are payments to providers for covered services.

If incurred claims do not include amounts an MA organization pays to individuals or entities that are not providers for supplemental benefits, including SSBCI, under current rules these expenditures could still potentially be included in the MLR numerator as expenditures related to quality improvement activities (QIAs). To be considered QIA-related expenditures under § 422.2430, the benefit must be an activity that falls into one or more of the categories listed in paragraph (a)(2) of that section, and it must be designed for the purposes listed in paragraph (a)(3): (1) To improve health quality; (2) to increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results; (3) to be directed toward individual enrollees, specific groups of enrollees, or other populations as long as enrollees do not incur additional costs for population-based activities; and (4) to be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations. Although we believe that supplemental benefits that meet the expanded ''primarily health related'' standard at proposed § 422.100(c)(2)(ii)(A) and non-primarily health related SSBCI described at proposed § 422.102(f) could potentially qualify as QIAs under § 422.2430, whether a particular benefit met all of the requirements of that regulation would need to be determined on a case-by-case basis. With our proposal, this case-by-case determination would no longer be necessary for services that are covered under the plan benefit package offered by an MA plan pursuant to the statute and regulations governing the MA program; all expenditures for covered services would be included in the incurred claims portion of the MLR numerator.

We believe that including in the MLR numerator amounts MA organizations spend on supplemental benefits that meet the ''primarily health related standard'' at proposed § 422.100(c)(2)(ii)(A) and on non-primarily health related SSBCI under proposed § 422.102(f) is consistent with the purpose of the MA MLR requirement. As explained in the May 2013 Medicare MLR final rule adopting the MLR regulations (78 FR 31284), the MLR requirement creates an incentive for MA organizations to reduce administrative costs such as marketing costs, profits, and other uses of plan revenues, and to help ensure that taxpayers and enrolled beneficiaries receive value from Medicare health plans.

In order to ensure that the MLR numerator includes amounts MA organizations spend on supplemental benefits that are ''primarily health related'' under proposed § 422.100(c)(2)(ii)(A) and on non-primarily health related SSBCI under proposed § 422.102(f), we propose to modify the regulation at § 422.2420(b)(2)(i) to remove the specification that incurred claims are direct claims that an MA organization pays *to providers* for covered services provided to all enrollees under the contract. We also propose to remove the specification that incurred claims include payments under capitation contracts *with physicians.* Finally, we propose to replace the phrase ''direct claims,'' which customarily refers to billing invoices providers submit to payers for reimbursement, with the general term ''amounts.'' As amended, § 422.2420(b)(2)(i) would include in incurred claims all amounts that an MA organization pays (including under capitation contracts) for covered services, regardless of whether the recipient of the payment is a provider as defined in § 422.2. Including in incurred claims amounts spent on these expanded supplemental benefits, as proposed, avoids creating uncertainty over whether payments for such services could otherwise be included in the MLR numerator (for example, as QIA-related expenditures), and it is consistent with our determination in the May 2013 Medicare MLR final rule (78 FR 31289) that incurred claims should reflect the benefit design under the contract.

3. Codifying Current Definitions of Partial, Full, and Non-Credibility and Credibility Factors (§§ 422.2440 and 423.2440)

The regulations at §§ 422.2440 and 423.2440 provide for the application of a credibility adjustment to the medical loss ratios (MLRs) of certain MA and Part D contracts with relatively low enrollment. A credibility adjustment is a method to address the impact of claims variability on the experience of smaller contracts by adjusting the MLR upward. As discussed in the February 23, 2013 Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule (78 FR 12428, 12438) (hereinafter referred to as the ''February 2013 Medicare MLR proposed rule''), for contracts with fewer members, random variations in the claims experience of enrollees could cause a contract's reported MLR to be considerably below or above the statutory requirement in any particular year, even though the MA organization or Part D sponsor estimated in good faith that the combination of the projected revenues and projected claims would produce an MLR that meets the statutory 85 percent minimum MLR requirement. The MLR credibility adjustments address the effect of this random variation by increasing the MLR of smaller contracts, thereby reducing the probability that such contracts will fail to meet the minimum MLR requirement simply because of random claims variability.

Whether a contract receives a credibility adjustment depends on the extent to which the contract has credible experience. A contract with credible experience is one that covers a sufficient number of beneficiaries for its experience to be statistically valid. A contract with fully credible experience has sufficient data to expect that the statistical variation in the reported MLR is within a reasonably small margin of error and will not receive a credibility adjustment under §§ 422.2440(b) and 423.2440(b). A contract has non-credible experience if it has so few beneficiaries that it lacks valid data to determine whether the contract meets the MLR requirement. Under §§ 422.2440(c) and 423.2440(c), a contract with non-credible experience is not subject to sanctions for failure to meet the 85 percent MLR requirement. A contract has partially credible experience if it exceeds the enrollment threshold for non-credible experience but does not have a sufficient number of enrollees for its experience to be fully credible. For contracts with partially credible

experience, a credibility adjustment adds additional percentage points to the MLR in recognition of the statistical unreliability of the underlying data.

In the May 2013 Medicare MLR final rule (78 FR 31284, 31295–96), CMS published the definitions of partial, full, and non-credibility and the credibility factors for partially credible MA and Part D contracts for contract year 2014. The factors appear in proposed Table 1 to § 422.2440 and proposed Table 1 to § 423.2440. Consistent with that final rule and regulations at §§ 422.2440 and 423.2440, for contract years 2015 through 2020, we have finalized through the annual Advance Notice and Rate Announcement process the continued use of these definitions and credibility factors.

We believe that the definitions of partial, full, and non-credibility and the credibility factors published in the May 2013 Medicare MLR final rule continue to appropriately address the effect of random claims variability on the MLRs of low enrollment MA and Part D contracts. However, we believe that it is more consistent with the policy and principles articulated in Executive Order 13892 on Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication (October 9, 2019) that we define and publish the definitions of partial, full, and non-credibility and the credibility factors in the **Federal Register**, and that we codify these definitions and factors in the Code of Federal Regulations, as opposed to defining and publishing these terms and factors through the annual Advance Notice and Rate Announcement process. Therefore, we are proposing to amend the regulations at §§ 422.2440 and 423.2440 to codify in regulation text the definitions of partial, full, and non-credibility and the credibility factors that CMS published in the May 2013 Medicare MLR final rule (78 FR 31296). First, we propose to amend paragraph (d) of §§ 422.2440 and 423.2440 by removing the current text (which states that CMS will define and publish definitions of partial, full, and non-credibility and the credibility factors through the annual Advance Notice and Rate Announcement process) and adding new paragraphs (d)(1) through (3) to specify ranges for the number of member months at which a contract's experience is, respectively, partially credible, fully credible, or non-credible. We propose that the number of member months at which a contract's experience is defined as partially credible, fully credible, or non-credible be the same as the values that were used define each of those terms in the May 2013 Medicare MLR final rule. Thus, for MA contracts, we propose that a contract is partially credible if it has at least 2,400 member months and fewer than or equal to 180,000 member months, fully credible if it has more than 180,000 member months, and non-credible if it has fewer than 2,400 member months. For Part D contracts, we propose that a contract is partially credible if it has at least 4,800 member months and fewer than or equal to 360,000 member months, fully credible if it has more than 360,000 member months, and non-credible if it has fewer than 4,800 member months. We propose to amend paragraphs (a), (b), and (c) of both §§ 422.2440 and 423.2440 by removing the text which provides that CMS determines whether a contract's experience is partially credible, fully credible, or non-credible, respectively, and by adding new language specifying that partially credible experience is defined at (d)(1), fully credible experience is defined at (d)(2), and non-credible experience is defined at (d)(3).

At § 422.2440, we propose to add new paragraph (e) to address the credibility adjustment for partially credible contracts. We propose at paragraph (e)(1) that, for partially credible MA contracts other than MSA contracts, the credibility adjustment is the base credibility factor determined under proposed paragraph (f). At proposed paragraph (f), we propose to specify that the base credibility factor for a partially credible MA contract is determined based on the number of member months and the factors in proposed Table 1 to § 422.2440. Proposed paragraph (f) also states the rules for using proposed Table 1 to § 422.2440 to identify the base credibility factor: (i) When the number of member months for a partially credible MA contract exactly matches the amount in the ''Member months'' column in proposed Table 1 to § 422.2440, the value associated with that number of member months is the base credibility factor; and (ii) the base credibility factor for a number of member months between the values shown in proposed Table 1 to § 422.2440 is determined by linear interpolation.

At § 423.2440, we propose to add new paragraph (e), which provides that for partially credible Part D contracts, the applicable credibility adjustment is determined based on the number of member months and the factors in proposed Table 1 to § 423.2440. Proposed paragraph (e) states the rules for using proposed Table 1 to § 423.2440 to identify the base credibility factor: (1) When the number of member months used to determine credibility exactly matches a member month category listed in proposed Table 1 to § 423.2440, the value associated with that number of member months is the credibility adjustment; and (ii) the credibility adjustment for a number of member months between the values shown in proposed Table 1 to § 423.2440 is determined by linear interpolation.

To illustrate linear interpolation, if the number of member months for an MA contract falls between two values in proposed Table 1 to § 422.2440, the base credibility factor would be calculated by first determining where, by percentage of the difference between those two values, the number of member months falls. Thus, if an MA contract has 10,000 member months, its number of member months falls 66.7 percent of the way between 6,000 and 12,000 (equal to $(10{,}000 - 6{,}000) \div (12{,}000 - 6{,}000)$). This percentage is multiplied by the difference between the base credibility factors corresponding to the number of member months in proposed Table 1 to § 422.2440; $0.667 * (0.053 - 0.037) = 0.011$. To find the base credibility factor, this amount is subtracted from the factor corresponding to the lower number of member months in proposed Table 1 to § 422.2440. Thus, $0.053 - 0.011$ is equal to 0.042, or 4.2 percent, which is the base credibility factor for an MA contract with 10,000 member months.

4. Deductible Factor for MA Medical Savings Account (MSA) Contracts (§ 422.2440)

We are proposing to include in the MLR calculation an additional adjustment factor for MA medical savings account (MSA) contracts that receive an MLR credibility adjustment. Specifically, we are proposing that the credibility adjustment for partially credible MA MSA contracts will be calculated by multiplying the applicable base credibility factor in proposed Table 1 to § 422.2440 by a ''deductible factor.'' This additional adjustment for MA MSAs is intended to recognize that the variability of claims experience is greater under health insurance policies with higher deductibles than under policies with lower deductibles, with high cost or outlier claims representing a larger portion of the overall claims experience of plans with high deductibles. As a result, a contract with a high average deductible is more likely to report a low MLR than is a contract with the same number of enrollees but with a low average deductible. As under the commercial MLR rules, the proposed deductible-based adjustment would only apply to contracts that receive a credibility adjustment due to low enrollment. We believe that a

contract with experience that is fully credible has sufficient data to expect that the statistical variation in the reported MLR is within a reasonably small margin of error, regardless of the deductible level.

As explained in the February 2013 Medicare MLR proposed rule (78 FR 12428), CMS used the MLR rules that apply to issuers of employer group and individual market private insurance (referred to hereafter as the ''commercial MLR rules'') as a reference point for developing the MLR rules for MA and Part D (referred to hereafter as the ''Medicare MLR rules''). We sought to align the commercial and Medicare MLR rules in order to limit the burden on organizations that participate in both markets, and to make commercial and Medicare MLRs as comparable as possible for comparison and evaluation purposes, including by Medicare beneficiaries. However, we recognized that some areas of the commercial MLR rules would need to be revised to fit the unique characteristics of the MA and Part D programs. One way in which the Medicare MLR rules currently deviate from the commercial rules is the omission of a deductible-based adjustment to the Medicare MLR calculation. The rationale given in the February 2013 Medicare MLR proposed rule for omitting a deductible factor from the Medicare MLR calculation was that Medicare deductibles were more confined than deductibles in the commercial market, and that we believed that the limited range of Medicare cost sharing did not prompt the need for such an adjustment (78 FR 12439).

Although we continue to believe that deductibles for most MA and Part D contracts are too low to necessitate the adoption of a deductible factor for all contracts, we now recognize that the February 2013 Medicare MLR proposed rule's rationale for excluding a deductible factor from the Medicare MLR calculation did not adequately take into account the specific characteristics of MA MSA plans, which tend to have much higher deductibles than other MA plan types. (For contract year 2020, the average deductible is $454 for MA plans (excluding MA MSAs) and $6,000 for MA MSAs.) We note that, under the commercial MLR regulations at 45 CFR part 158, a deductible factor applies to the credibility adjustment of issuers of employer group and private health insurance plans that have an average deductible of $2,500 or higher. For contract year 2020, all MA MSAs have deductibles in excess of $2,500. These significantly higher deductibles in MSA plans cause MA MSA contracts to have more variability in their claims experience relative to MA contracts with the same number of enrollees but lower deductibles. To the extent that this variability in claims experience and its potential impact on the MLR calculation has deterred MA organizations from offering an MSA product, the proposed addition of a deductible factor to the MLR calculation for MA MSAs would serve to encourage the offering of MA MSA plans by eliminating the current inconsistency in how the commercial and Medicare MLR rules take into account the greater variability of claims experience under health insurance policies with high deductibles.

The proposal to add a deductible factor to the MLR calculation for MA MSA contracts also aligns with the directive in Executive Order 13890 on Protecting and Improving Medicare for Our Nation's Seniors (October 3, 2019) for the Secretary to take actions that ''encourage innovative MA benefit structures and plan designs, *including through changes in regulations and guidance that reduce barriers to obtaining Medicare Medical Savings Accounts . . . .*'' (emphasis added). Currently, for many Medicare beneficiaries, the greatest barrier to enrolling in an MA MSA is the lack of MA MSA plans in the beneficiary's area of residence. For contract year 2020, MA MSA plans are only available in 27 states and the District of Columbia. The omission of a deductible-based adjustment from the current Medicare MLR regulations could contribute to the limited availability of MA MSAs for Medicare beneficiaries because the greater variability in the MLR for contracts with high average deductibles—and the resulting higher risk of a potential remittance to CMS or sanctions under § 422.2410—could dissuade MA organizations from offering plans of this type. We believe that, if the proposed change is finalized, MA organizations would be less likely to be deterred from offering MA MSAs out of concern that the MA MSA contract would be at risk of failing to meet the MLR requirement due to random variations in claims experience.

We propose to adopt the same deductible factors that apply under the commercial MLR regulations at 45 CFR part 158. As noted in the Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act Interim Final Rule (75 FR 74864, 74881–82, published December 1, 2010), the commercial deductible factors were based on an actuarial analysis of anticipated claims experience in the commercial market by actuarial consultants to the National Association of Insurance Commissioners (NAIC). Our preference is to use Medicare data to develop the deductible factors that apply to MA MSAs, and we are working to assess how to use Medicare data for this purpose. We believe that the commercial deductible factors are suitable for adjusting MSA MLRs in the absence of Medicare-specific deductible factors because the commercial factors are designed to take into account the variability in claims experience resulting from similarly high deductibles. In order to advance the use of MSAs in the MA program, we are proposing to apply the commercial deductible factors in the MLR calculation for MA MSAs. We intend to assess the feasibility of developing deductible factors using Medicare data. We solicit comment on whether and how Medicare data should be used to evaluate whether the difference in variability between MLRs for MSA plans and non-MSA plans necessitates the use of Medicare-specific deductible factors, as well as how Medicare data could be used to develop Medicare-specific deductible factors. We also solicit comment on whether and how the proposed deductible factors should be adjusted to account for any unique features of the Medicare MLR rules (for example, the inclusion of the MA MSA deposit amount in the Medicare MLR numerator and denominator), or to reflect any differences between the commercial and Medicare MLR rules (such as the commercial rules' lower minimum MLR requirement for small group and individual health insurance plans (80 percent, compared to the Medicare rules' 85 percent MLR requirement for all contracts)). We solicit comment on potential consequences of the application of a deductible factor to the MLR calculation for MA MSA contracts, such as impacts on benefits for enrollees in MSA plans.

We propose new § 422.2440(e)(2) to specify that the credibility adjustment for an MA MSA contract will be the base credibility factor determined under proposed paragraph (f), multiplied by the deductible factor determined under proposed paragraph (g). At proposed paragraph (g), we specify that the applicable deductible factor for an MA MSA contract will be based on the enrollment-weighted average deductible for all MSA plans under the contract, where the deductible for each plan under the contract is weighted by the plan's portion of the total number of member months for all plans under the contract during the contract year for

which the MLR is being calculated. (We note that all MA plans under an MA MSA contract must be MSA plans, and MSA plans may only be offered under MSA contracts.) When the weighted average deductible for a contract exactly matches the amount in the ''Weighted average deductible'' column in proposed Table 2 to § 422.2440, the value associated with that weighted average deductible is the deductible factor. The deductible factor for a weighted average deductible between the values shown in proposed Table 2 to § 422.2440 is determined by linear interpolation.

To illustrate calculation of the credibility adjustment for a partially credible MA MSA contract, if enrollment under an MA MSA totals 24,000 member months, the base credibility factor in proposed Table 1 to § 422.2440 is 2.6 percent. If the contract's weighted average deductible is $5,000, the deductible factor in proposed Table 2 to § 422.2440 is 1.402. The credibility adjustment is calculated by multiplying the base credibility factor by the deductible factor; 0.026 * 1.402 = 0.036. Thus, the credibility adjustment is 3.6 percent.

If an MA MSA contract has a weighted average deductible that falls between two values in proposed Table 2 to § 422.2440, the deductible factor is calculated by first determining where, by percentage of the difference between those two values, the weighted average deductible falls. Thus, if an MA MSA has a weighted average deductible of $8,000, its weighted average deductible falls 60 percent of the way between $5,000 and $10,000 (equal to ($8,000 − $5,000) ÷ ($10,000 − $5,000)). This percentage is multiplied by the difference between the deductible factors corresponding to the weighted average deductibles in proposed Table 2 to § 422.2440; 0.60 * (1.736 − 1.402) = 0.200. To find the deductible factor, this amount is added to the factor corresponding to the lower weighted average deductible in proposed Table 2 to § 422.2440. Thus, 1.402 + 0.2 is equal to 1.602, which is the deductible factor for a weighted average deductible of $8,000.

J. Dismissal and Withdrawal of Medicare Part C Organization Determination and Reconsideration and Part D Coverage Determination and Redetermination Requests (§§ 422.568, 422.570, 422.582, 422.584, 422.590, 422.592, 422.631, 422.633, 423.568, 423.570, 423.582, 423.584, and 423.600)

We are proposing regulations for withdrawing or dismissing Part C organization determination and reconsideration requests and Part D coverage determination and redetermination requests. We are also proposing regulations for withdrawing or dismissing Part C and Part D independent review entity (IRE) reconsiderations. A withdrawal of a request is when the party that initiated the request voluntarily decides that a decision on their request is no longer needed, and the party communicates that desire to the plan to stop consideration of the request for determination (or reconsideration). A dismissal of a request is when a plan decides to stop consideration of a request before issuing a decision. The effect of both a withdrawal and a dismissal is that the plan does not proceed with making a substantive decision on the merits of the coverage request.

Under § 422.562(d)(1), which provides that unless subpart M provides otherwise, and subject to specific exclusions set forth in paragraph (d)(2), the regulations in part 405 (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act) apply to MA cases to the extent they are appropriate. Given that the dismissal requirements in § 405.952 apply to withdrawal or dismissal of a request for a redetermination (which is the first level of appeal in the Medicare fee-for-service (FFS) program), we believe the applicability of those provisions is generally limited to Part C plan level reconsiderations but not to initial organization determinations. In addition, we believe the requirements at § 405.972 are generally applicable to withdrawal or dismissal of a reconsideration by the independent review entity under the provisions of § 422.562(d)(1). For Part D requests, the regulations at part 423, subpart U, apply to cases reviewed by the Office of Medicare Hearings and Appeals (OMHA) and the Appeals Council. Currently, the Part D withdrawal and dismissal procedures applicable to Part D plan sponsors is communicated through sub-regulatory guidance.

In the absence of Part C and Part D regulations related to withdrawal and dismissal of requests that are under consideration at the plan level, we have observed through plan audits and inquiries that MA organizations and Part D plan sponsors utilize § 405.952 as a guide for handling the withdrawal and dismissal of initial requests for coverage (that is, organization determinations and coverage determinations) and plan level appeals from those decisions (that is., reconsiderations). Based on the number of inquiries CMS has received regarding withdrawal and dismissal of Part C organization determinations and reconsiderations and Part D coverage determinations and redeterminations, we are proposing rules that would apply when these procedural actions are taken. These proposals would codify what we believe to be the current practices related to dismissal of Part C organization determination and reconsideration requests and Part D coverage determination and reconsideration requests, including those applicable to the Part C and Part D IRE. The proposals would also apply to requests for integrated organization determinations and reconsiderations at §§ 422.631 and 422.633. The proposals specifically address under what circumstances it would be appropriate to dismiss a coverage request or appeal at the plan or IRE level. We are also proposing rules for how a party may request to withdraw their coverage request or appeal at the plan or IRE level. The proposed requirements would be consistent across both Part C and Part D and would be as follows:

- In proposed new §§ 422.568(g), 422.631(e), and 423.568(i), we are proposing to permit a plan to dismiss a request for the initial plan level decision (that is, organization determination, integrated organization determination or coverage determination) when any of the following apply—

++ The individual or entity making the request is not permitted to request an organization determination or coverage determination.

++ The plan determines that the individual or entity making the request failed to make a valid request for an organization determination or coverage determination.

++ The enrollee dies while the request is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the organization determination or coverage determination; we note that we interpret having a financial interest in the case as having financial liability for the item(s) or service(s) underlying the coverage request.

++ The individual or entity who requested the review submits a timely written request for withdrawal of their request for an organization determination or coverage determination with the plan.

- In proposed §§ 422.570(g) and 423.570(f), we are proposing to permit a plan to dismiss an expedited organization determination or coverage determination, consistent with the proposed requirements at §§ 422.568

and 423.568, respectively. Applicability of these procedures to expedited integrated coverage determinations is described in proposed § 422.631(e).

• In proposed §§ 422.582(f), 422.633(h), and 423.582(e), we are proposing to permit a plan to dismiss (either entirely or as to any stated issue) a request for the second plan level decision (that is, reconsideration, integrated reconsideration or redetermination) when any of the following apply—

++ The individual or entity making the request is not a proper party to the reconsideration, integrated reconsideration, or redetermination under the applicable regulation; we mean this to authorize dismissal when the individual or entity making the request is not permitted to request a reconsideration, integrated reconsideration, or redetermination.

++ When the plan determines the party failed to make a valid request for a reconsideration, an integrated reconsideration, or a redetermination that substantially complies with the applicable regulation for making a valid request for reconsideration or redetermination.

++ When the party fails to file the reconsideration, integrated reconsideration or redetermination request within the proper filing time frame in accordance with the applicable regulation.

++ When the enrollee dies while the reconsideration or redetermination is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the reconsideration or redetermination. We interpret having a financial interest in the case as having financial liability for the item(s) or service(s) underlying the coverage request.

++ When the individual or entity submits a timely written request to withdraw their request for a reconsideration or redetermination.

• At new § 422.584(g), we are proposing to permit a plan to dismiss an expedited reconsideration using virtually identical language as for the proposed requirements at § 422.582. At new § 423.584(f), we are proposing to permit a plan to dismiss an expedited redetermination by cross referencing § 423.582. Applicability of these procedures to expedited integrated coverage determinations is described in proposed § 422.633(h).

• At new §§ 422.592(d) and 423.600(g), we are proposing to permit the Part C and Part D IRE to dismiss a request when any of the following apply—

++ The individual or entity is not a proper party under § 422.578(c) in the case of a Part C reconsideration or is not permitted to request a reconsideration by the IRE under § 423.600(a) in the case of a Part D reconsideration.

++ The independent entity determines the party failed to make out a valid request for a reconsideration that substantially complies with the applicable regulation.

++ When the enrollee dies while the reconsideration request is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the reconsideration. We interpret having a financial interest in the case as having financial liability for the item(s) or service(s) underlying the coverage.

++ When the individual or entity submits with the independent review entity a timely written request for a withdrawal of the reconsideration.

• In proposed §§ 422.568(h), 422.582(g), 422.592(e), 422.631(f), 422.633(i), 423.568(j), 423.582(f), and 423.600(h) we are proposing that written notice of the dismissal must be delivered to the parties (either mailed or otherwise transmitted) to inform them of the action; this would include the individual or entity who made the request. The notice must include certain information, as appropriate, including applicable appeal rights (that is, request to vacate dismissal, review of the dismissal).

• In proposed §§ 422.568(i), 422.582(h), 422.592(f), 422.631(g), 422.633(j), 423.568(k), 423.582(g), and 423.600(i), we are proposing that a dismissal may be vacated by the entity that issued the dismissal (that is, MA organizations, applicable integrated plans, Part D plan sponsors, and the IRE) if good cause for doing so is established within 6 months of the date of the date of the dismissal.

• In proposed §§ 422.568(j), 422.631(h), and 423.568(l), we are proposing that the dismissal of the organization determination or coverage determination is binding unless it is vacated by the MA organization, applicable integrated plan, or Part D plan sponsor, as applicable.

• At new §§ 422.582(i), 422.633(k), and 423.582(h), we are proposing that the dismissal of the reconsideration or redetermination is binding unless the enrollee or other valid party requests review by the IRE or the dismissal is vacated under the applicable regulation.

• At new §§ 422.592(g) and 423.600(j), we are proposing that a dismissal by the IRE is binding and not subject to further review unless a party meets the amount in controversy threshold requirements necessary for the right to a review by an administrative law judge or attorney adjudicator and the party files a proper request for review with the Office of Medicare Hearings and Appeals as outlined in §§ 422.600, 422.602, and 423.600(j), as applicable.

• At new §§ 422.568(k), 422.592(h), 422.631(i), 422.633(g), 423.568(m), and 423.600(f), we are proposing that a party that makes a request may withdraw its request at any time before the decision is issued by filing a written request for withdrawal. Each proposed regulation paragraph identifies the entity (that is, the MA organization, the applicable integrated plan, or the Part D plan) with which the request for withdrawal must be filed.

We are also proposing a change that applies to Part C only, given that the current rules do not include a process for an enrollee or other party to request IRE review of an MA organization's reconsideration. Specifically, we are proposing to add a new paragraph (h) to § 422.590 that would give the enrollee or another party to the reconsideration the right to request review by the independent entity of an MA organization's dismissal of a request for a reconsideration in accordance with §§ 422.582(f) and 422.584(g). We believe this proposed language is necessary because there is currently no process specified in regulation for an MA enrollee or another party to request review by the independent entity of an MA organization's reconsideration. We are also proposing at new paragraph (h) of § 422.590 that a request for review of such a dismissal must be filed in writing with the independent entity within 60 calendar days from the date of the MA organization's dismissal notice. Under existing rules at § 422.590(a)(2), (b)(2), (c)(2), (d), (e)(5), and (g),[63] if the MA organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a reconsideration (or no later than the expiration of an applicable extension). These regulations that require a case to be automatically sent to the independent entity do not

[63] We note that § 422.590 was extensively amended by the April 2019 final rule, effective January 1, 2020.

apply in the case of a dismissal of a request for a reconsideration because the MA organization is not making a substantive decision on the merits of the request. In other words, if the MA organization dismisses a reconsideration request, this does not constitute an affirmation of an adverse organization determination decision and, therefore, the case is not subject to being automatically forwarded to the independent entity. Under the current process established through an HPMS memo issued September 10, 2013 and effective January 1, 2014, MA organizations dismiss reconsideration requests, when appropriate, and provide notice of the dismissal, including informing enrollees and other parties of the opportunity to request that the independent entity review the dismissal. The proposal to add a new paragraph (h) to § 422.590 seeks to establish in regulation the right of enrollees and other parties to request review by the independent entity of the MA organization's dismissal of a request for a reconsideration in accordance with §§ 422.582(f) and 422.584(g).

As a corollary to this proposal, we are also proposing to revise paragraph (a) of § 422.592 to state that, consistent with proposed § 422.590(h), the independent entity is responsible for reviewing MA organization dismissals of reconsideration requests. Further, we are proposing a new paragraph (i) at § 422.592 to state that the independent entity's decision regarding an MA organization's dismissal, including a decision to deny a request for review of a dismissal, is binding and not subject to further review. Under this proposal, if the independent entity determines that the MA organization's dismissal was in error, the independent entity would vacate the dismissal and remand the case to the plan for reconsideration. In such cases, the MA organization must accept the remand from the independent entity and consider the substance of the reconsideration request. Again, this proposal is consistent with existing guidance on the processing of dismissals of requests for an MA organization reconsideration and should be familiar to MA organizations and the independent review entity.

We are also proposing a change that applies to Part D only, given that the current rules do not include a process for enrollees to request IRE review of plan sponsor dismissals of redetermination requests. Under existing rules at § 423.600(a), an enrollee may request reconsideration from the IRE of a plan sponsor's redetermination, but there is no existing regulatory mechanism for an enrollee to seek IRE review if a plan takes the procedural action of dismissing a redetermination request.

We are proposing to add a new paragraph (f) at § 423.582 to establish in regulation the right of enrollees and other parties to request review by the independent entity of the Part D plan sponsor's dismissal of a request for a redetermination. As a corollary to this proposal, we are also proposing to add paragraph (j) at § 423.590 to state that, consistent with proposed § 423.584(f), an enrollee can request review of a Part D plan sponsor's dismissal of a redetermination request by the independent entity. Further, we are proposing a new paragraph (k) at § 423.600 to state that if the independent entity determines that the Part D plan sponsor's dismissal was in error, the independent entity would reverse the dismissal and remand the case to the plan for a redetermination on the merits of the case. We believe this proposed language is necessary because there is currently no process specified in regulation for a Part D enrollee or another party to request review by the independent entity of a Part D plan sponsor's dismissal.

Although creating a process for enrollees to request IRE review of a Part D plan sponsor dismissal of redetermination request is not simply codifying current practice, we have not included a Regulatory Impact Analysis for this provision in the Collection of Information section because this change is technical in nature, but seek comment on this assumption. It aligns language for Part C and Part D. For the reasons given in the next paragraph, we believe it will have no impact.

Plan dismissals in Part D are different than plan dismissals in Part C. In Part C, a plan may dismiss an organization determination request for a number of reasons. However, Part D plan level dismissals tend to be purely administrative (for example, pertaining to a lack of proper submission). For that reason, the number of plan level dismissals in Part D is much lower than in Part C. Additionally, because Part D dismissals are administrative, in most cases it will be more prudent and expeditious for a party to resubmit their coverage determination request with the correct information than to request independent review of the dismissal. Requesting independent review of a dismissal will add increased paperwork and time. Therefore, while it is important to have parity and consistency between the regulations in FFF, Part C and Part D, we do not believe there will be many, if any, requests for independent review of Part D plan level dismissals.

These proposed rules generally mirror the current FFS rules at §§ 405.952 and 405.972 to the extent we believe is appropriate. We believe it is appropriate to base these proposed rules on the existing FFS rules related to withdrawal and dismissal of requests given the applicability, to the extent appropriate, of those rules to Part C per § 422.562(d)(1), as well as the observed current practices of both MA organizations and Part D plan sponsors. We believe that codification of these procedures will reduce confusion and promote consistent and proper handling of withdrawals and dismissals. Furthermore, we believe these proposals will be beneficial to enrollees because there will be clarity and consistency in how plans process these actions. We are not scoring this provision in the Regulatory Impact Analysis section since it codifies existing guidance, but seek comment on this assumption. We believe all stakeholders are already following the current guidance. We are also not scoring this provision in the Collection of Information section since the filing of an appeal is an information collection associated with an administrative action pertaining to specific individuals or entities and thus exempt from Paperwork Reduction Act requirements under 5 CFR 1320.4(a)(2) and (c). We welcome comments on these proposals.

We believe that the proposed addition of parallel provisions regarding dismissals and withdrawals to the integrated organization determination and integrated reconsideration procedures at §§ 422.631 and 422.633 also reflect current D–SNP operations. We seek comment, however, on whether these rules could create inconsistencies with any state-specific Medicaid procedures pertaining to dismissals or withdrawals. We note that under § 422.629(c), states have the ability through their contracts with D–SNPs to require more stringent beneficiary protections regarding timeframes and notices. We encourage commenters to consider if any Medicaid-related inconsistencies could be addressed through such contractual language and to submit comments on this topic.

We also request comment whether additional clarification or regulatory changes are necessary to ensure smooth operations for MA organizations, applicable integrated plans, or Part D plans in connection with implementing this proposal or if additional beneficiary protections need to be addressed. We believe that this proposal would streamline and standardize processes

while empowering beneficiaries in these plans to take steps to withdraw their appeals when they like. Further, by clarifying the authority for plans and IREs to dismiss coverage requests and appeals where there is no longer a financial interest for any enrollee or where the minimum standards for the content and timing of a request are not met, we hope to minimize administrative burden for plans.

K. Methodology for Increasing Civil Money Penalties (CMPs) (§§ 422.760 and 423.760)

CMS may impose civil money penalties (CMPs) on MA organizations and Part D sponsors for certain regulatory offenses, as described in subpart O of 42 CFR parts 422 and 423. Sections 1857(g)(3)(A) and 1860D–12(b)(3)(E) of the Act provides CMS with the ability to impose CMPs of up to $25,000 per determination (determinations are those which could otherwise support contract termination, pursuant to § 422.509 or § 423.510), as adjusted annually under 45 CFR part 102, when the deficiency on which the determination is based adversely affects or has the substantial likelihood of adversely affecting an individual covered under the organization's contract. The current regulations mirror the statute with respect to the amount of the penalty that CMS may impose for a per determination (contract level) penalty. Additionally as specified in §§ 422.760(b)(2) and 423.760(b)(2) CMS is permitted to impose CMPs of up to $25,000, as adjusted annually under 45 CFR part 102, for each Part D enrollee directly adversely affected or with a substantial likelihood of being adversely affected by a deficiency.

CMS has the authority to issue a CMP up to the maximum amount permitted under regulation, as adjusted annually [64] for each affected enrollee or per determination. The statute and the existing regulations afford the agency wide discretion to calculate CMPs. CMS does not apply the maximum penalty amount authorized under regulation, in all instances because the penalty amounts under the current CMP calculation methodology are sufficient to encourage compliance with CMS rules. On December 15, 2016, CMS released on its website, the first public CMP calculation methodology for calculating CMPs for MA organizations and Part D sponsors starting with referrals received in 2017. On March 15, 2019, CMS released for comment a proposed CMP calculation methodology on its website that revised some portions of the methodology released in December 2016. Subsequently, on June 21, 2019, CMS finalized the revised CMP calculation methodology document, made it available on its website, and applied it to CMPs issued starting with referrals received in contract year 2019 and beyond. CMS also indicated in the revised June 2019 CMP calculation methodology that CMS would memorialize the approach to increase minimum penalty amounts in regulation, which is specified in this proposal.[65]

CMS calculates the CMP amount for each deficiency by applying a standard formula. Under the standard formula, CMS applies a standard penalty amount (based on whether the deficiency should be calculated on a per enrollee or per determination basis) to the deficiency, and adjusts it for any factors that contributed to the deficiency (that is, aggravating factors). If the penalty for a deficiency is calculated on a per determination basis pursuant to §§ 422.760(b)(1) and 423.760(b)(1), the penalty amount is multiplied by the number of affected contracts. If a penalty for a deficiency is calculated on a per enrollee basis pursuant to §§ 422.760(b)(2) and 423.760(b)(2), the penalty amount is multiplied by the number of affected enrollees.

The Federal Civil Penalties Inflation Adjustment Act Improvement Act of 2015 (Sec. 701 of Pub. L. 114–74) requires agencies to adjust the maximum CMP amounts for inflation annually. The Office of Management and Budget (OMB) releases the cost-of-living multiplier agencies must use to calculate penalty increases for the following year.[66] CMS, however, has the discretion to set CMP amounts below the maximum amount required by law. CMS proposes increasing the per determination and per enrollee standard minimum penalty amounts and associated aggravating factors by multiplying the standard minimum penalty amounts by the cost-of-living multiplier published annually by OMB.[67]

CMS proposes to update the minimum penalty and aggravating factor amounts no more often than every 3 years. Historically, CMS has audited Part C and D organizations on a three-year audit cycle. Therefore, CMS proposes to update penalty amounts consistent with this schedule in an effort to subject organizations audited within the same audit cycle to the same penalty amounts. When the standard penalty amount is updated, CMS proposes to increase the penalty amounts that would have been applied if CMS had multiplied the standard penalty amounts by the cost-of-living multiplier each year during the preceding 3-year period. CMS also proposes to track the accrual of the standard penalty and aggravating factor penalty amounts and announce them on an annual basis. CMS proposes to codify this minimum penalty adjustment process by adding a new paragraph (b)(3) to §§ 422.760 and 423.760, and redesignating current paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5).

VI. Codifying Existing Part C and D Program Policy

A. Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101)

Section 1852(b)(1) of the Act prohibits discrimination by MA organizations on the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals. Under the authority of sections 1852(b)(1)(A), 1856(b)(1), and 1857(e)(1) of the Act, CMS added §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3), effective for coverage in 2011, to require all MA plans (including employer group waiver plans (EGWPs) and special needs plans (SNPs)) to establish limits on enrollee out-of-pocket cost sharing for Parts A and B services that do not exceed the annual limits established by CMS (75 FR 19709–11). We note that MA EGWPs must follow all relevant MA regulations and guidance unless CMS has

[64] Per the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which amended the Federal Civil Penalties Inflation Adjustment Act of 1990, the maximum monetary penalty amount applicable to 42 CFR 422.760(b), 423.760(b), and 460.46(a)(4) will be published annually in 45 CFR part 102. Pursuant to § 417.500(c), the amounts of civil money penalties that can be imposed for Medicare Cost Plans are governed by section 1876(i)(6)(B) and (C) of the Act, not by the provisions in part 422. Section 1876 solely references per determination calculations for Medicare Cost Plans. Therefore, the maximum monetary penalty amount applicable is the same as § 422.760(b)(1).

[65] See the ''Downloads'' section of the following CMS web page for the 2019 CMP Methodology and 2019 CMP Methodology Comments Responses Document: *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDEnforcementActions-.*

[66] See OMB Memorandum M–19–04 for the 2019 inflation adjustment multiplier. Available at: *https://www.whitehouse.gov/wp-content/uploads/2017/11/m_19_04.pdf.*

[67] Per OMB Memoranda M–19–04, *Implementation of Penalty Inflation Adjustments for 2019, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015,* published December 14, 2018, the cost-of-living adjustment multiplier for 2019 is 1.02522.

specifically waived a requirement under its 1867(i) statutory authority. Section 1858(b)(2) of the Act requires a limit on in-network and out-of-pocket expenses for enrollees in Regional Preferred Provider Organization (RPPO) MA plans. In addition, MA Local PPO (LPPO) plans, under § 422.100(f)(5), and RPPO plans, under section 1858(b)(2) of the Act and § 422.101(d)(3), are required to have two maximum out-of-pocket (MOOP) limits (also called catastrophic limits) established by CMS annually, including (a) an in-network and (b) a total catastrophic (combined) limit that includes both in-network and out-of-network items and services covered under Parts A and B. Relying on the same authority, we are proposing amendments to the regulations at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) to specify how these MOOP limits will be set for 2022 and subsequent years. In addition, our proposals here take into account statutory changes that are relevant to how CMS sets benefit category cost sharing limits. As discussed in section IV.A. of this proposed rule, section 17006 of the Cures Act amended section 1851(a)(3) of the Act to allow Medicare eligible beneficiaries with diagnoses of end-stage renal disease (ESRD) to choose a MA plan for Medicare coverage starting January 1, 2021, without the limits on such enrollment that currently apply.

CMS proposes to modify the regulations at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) to establish a methodology for setting the MOOP limits that takes into account how Medicare beneficiaries with diagnoses of ESRD will have greater access to MA plan coverage beginning with contract year 2021. Specifically, CMS proposes a multiyear transition that incorporates ESRD costs into the methodology for setting the MOOP limits. In addition, CMS proposes to provide additional transparency on how CMS determines up to three MOOP limits for local and regional plans by codifying the methodology for how MOOP limits will be set at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3). This proposal, in combination with section VI.B. of this proposed rule, aims to address potential stakeholder concerns regarding this program change and provide MA organizations with cost sharing flexibilities as an incentive to encourage more favorable benefit designs for beneficiaries. As noted in the 2020 Final Call Letter, CMS has an established policy of affording MA plans greater flexibility in establishing cost sharing for Part A and B benefits (that is, basic benefits) by adopting a lower, voluntary MOOP limit than is available to plans that adopt the higher, mandatory MOOP limit. In contract year 2020, CMS provided this flexibility, on varying levels, for a number of benefit categories. CMS expects adopting greater benefit design flexibilities will incentivize competition and result in greater access to MA plans with lower MOOP or cost sharing limits for enrollees. Codifying the flexibilities in regulation in advance of the 2022 and subsequent contract years to which they will apply will provide a measure of transparency and stability for the MA program and, we believe, encourage MA organizations to develop plan designs to take advantage of the flexibilities. In addition, we discuss potential factors that could trigger future rulemaking for determining MOOP limits.

Currently, local and regional PPO plans are required to have two MOOP limits consistent with maximum thresholds established by CMS, including (a) an in-network and (b) a catastrophic (combined) limit that includes both in-network and out-of-network items and services covered under Parts A and B. HMO–POS plans may offer out-of-network benefits as supplemental benefits, but are not required to have these services contribute to the in-network MOOP limit or to a combined in- and out-of-network MOOP limit. Although the MOOP limits apply to Parts A and B benefits, an MA organization can apply the MOOP limit to supplemental benefits as well. MA organizations are responsible for tracking out-of-pocket spending incurred by the enrollee (that is, cost sharing includes deductibles, coinsurance, and copayments, pursuant to § 422.2) and to alert enrollees and contracted providers when the MOOP limit is reached.

As stated in the April 2018 final rule, CMS currently sets MOOP limits based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Medicare Fee-for-Service (FFS). The Office of the Actuary (OACT) conducts an annual analysis to help CMS determine the MOOP limits using the most recent complete year's data and by projecting cost sharing using trend factors, such as enrollment changes and enrollment shifts between MA and original Medicare. The OACT bases its projections on actual claims data for Parts A and B benefits from the National Claims History files. Setting MOOP limits for 2020 was based on current regulation text at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) authorizing CMS to set MOOP limits to strike a balance between limiting costs to enrollees and changes in benefits, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages. The current mandatory MOOP limit represents approximately the 95th percentile of projected beneficiary out-of-pocket spending for the year to which the MOOP limit will apply. Stated differently, using the contract year 2020 MOOP limits as examples, 5 percent of Medicare FFS beneficiaries are expected to incur approximately $6,700 or more in Parts A and B deductibles, copayments, and coinsurance; the current voluntary MOOP limit of $3,400 represents approximately the 85th percentile of projected Medicare FFS out-of-pocket costs.

A strict application of the thresholds at the 95th and 85th percentile to set the MOOP limits since adoption of the MOOP regulations would have resulted in MOOP limits for MA LPPO and RPPO plans fluctuating from year-to-year. Therefore, CMS exercised discretion in order to maintain stable MOOP limits from year-to-year, when the established MOOP limits were approximately equal to the appropriate percentile. CMS took this approach in an effort to avoid enrollee confusion, allow MA plans to provide stable benefit packages year over year, and not discourage MA organizations from adopting the lower voluntary MOOP limit because of fluctuations in the amount.

MA plans may establish MOOP limits that are lower than the CMS-established maximum amounts. We currently consider any MOOP limit within the $0–$3,400 range as a voluntary MOOP and any MOOP limit within the $3,401–$6,700 range as a mandatory MOOP limit. The in-network MOOP limit dictates the combined MOOP range for PPOs (that is, PPOs are not permitted to offer a combined MOOP limit within the mandatory range, while having an in-network MOOP limit within the voluntary range). The combined MOOP limit for PPOs is calculated by multiplying the respective in-network MOOP limits by 1.5 for the relevant year and rounding to the nearest or lower $50 increment, similar to the proposal in paragraph (f)(4)(iii), if necessary.[68] Thus, the voluntary combined MOOP limit for PPOs in contract year 2020 was calculated as $3,400 × 1.5 = $5,100 (that is, an MA plan that establishes a dollar

[1] CMS. ''Benefits Policy and Operations Guidance Regarding Bid Submissions; Duplicative and Low Enrollment Plans; Cost Sharing Standards; General Benefits Policy Issues; and Plan Benefits Package (PBP) Reminders for Contract Year (CY) 2011'' (2010). Retrieved from *http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/downloads/dfb_policymemo04610final.pdf.*

limit within the $0–$5,100 range is using a lower, voluntary combined MOOP limit). Similarly, the mandatory combined MOOP limit for PPOs in contract year 2020 was calculated as $6,700 × 1.5 = $10,050, rounded down to the nearest $100 ($10,000) and MA plans that establish a dollar limit within the $5,101–$10,000 range are using a mandatory combined MOOP limit.

CMS currently affords greater flexibility in establishing Parts A and B cost sharing to MA plans that adopt a lower, voluntary MOOP limit (including PPO plans with a combined MOOP limit in the voluntary range) than is available to plans that adopt the higher, mandatory MOOP limit. The percentage of eligible Medicare beneficiaries with access to an MA plan (excluding employer and dual eligible special needs plans) offering a voluntary MOOP limit has decreased from 97.7 percent in contract year 2011 to 81.8 percent in contract year 2019. This has resulted in the percentage of total enrollees in a voluntary MOOP plan decreasing from 51 percent in contract year 2011 to 26 percent in contract year 2019.

We intend to continue use of more than one MOOP limit and are proposing, beginning with coverage for the 2022 contract year, to (1) establish explicit authority for up to three MOOP limits, including the current mandatory and voluntary MOOP limits and a third, intermediate MOOP limit; (2) codify the methodology for setting MOOP limits, and (3) adjust the methodology to take into account how the MA eligibility for Medicare beneficiaries is changing to remove the current limits on MA enrollment for Medicare eligible beneficiaries with diagnoses of ESRD. We believe that implementing more than two levels of MOOP and cost sharing limits will encourage plan offerings that result in more favorable benefit designs for beneficiaries. For example, increased access to plans with MOOP limits below the mandatory MOOP limit or lower cost sharing. We will monitor whether this change results in beneficiaries having access to plan offerings with MOOP limits below the mandatory MOOP limit or lower cost sharing over time and may consider additional changes through future rulemaking. By codifying the methodology for how these MOOP limits will be set, we are increasing the level of transparency for these policies and providing more stability and predictability to the MA program; MA organizations will have greater knowledge about how the MOOP limits are set and ability to anticipate where the MOOP limits will be in future years. For that reason, our proposal codifies our current practice with some revisions. In addition, as discussed in section VI.B. of this proposed rule, we are proposing to codify specific cost sharing limits and flexibility tied to use of the intermediate and lower voluntary MOOP limits by MA plans.

Under our proposal, we would substantially revise and restructure §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3). In the proposed revisions to these regulations, we are using the term ''basic benefits'' instead of referring to Medicare Part A and Part B benefits because the term ''basic benefits'' is now defined in § 422.100(c). We believe using the shorter, defined term increases the clarity and readability of the regulation. The proposed regulation text for these paragraphs avoids duplicate language where possible. We propose to codify the rules for setting the MOOP limits at § 422.100(f)(4). Currently, the same MOOP limits apply to MA local plans and to in-network limits for MA local and regional PPO plans. Therefore, we are proposing that § 422.101(d)(2), which imposes the MOOP limit for in-network MA regional plans, be revised to cross-reference the MOOP limits set for MA local plans at § 422.100(f)(4). Currently, the same MOOP limits apply to combined in-network and out-of-network out-of-pocket cost sharing for MA LPPO and RPPO plans and we intend to continue that policy. Therefore, we are proposing to use a cross-reference providing that the same MOOP limits apply under both § 422.100(f)(5) (for MA local PPOs) and § 422.101(d)(3) (for MA regional plans) for combined in-network and out-of-network cost sharing. By using these cross-references, we intend to clarify how certain MOOP limits are the same and to avoid repetitive regulation text. We are proposing to amend § 422.100(f)(4) to state the general rule that, except as provided in paragraph (f)(5), MA local plans must establish MOOP limits for basic benefits; as in the current regulation, proposed paragraph (f)(5) would address how the MOOP limits apply to the out-of-network coverage provided by local PPO plans. We also propose to include in §§ 422.100(f)(5) and 422.101(d)(2) the rules for PPOs in establishing in-network and combined (or catastrophic) MOOP limits. Finally, our proposal would codify in §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) the responsibility MA organizations have to track enrolled beneficiaries' out-of-pocket spending and to alert enrollees and contracted providers when the MOOP limit is reached. This is implicit in how a MOOP limit works, but we believe codifying these responsibilities emphasizes for MA organizations that these requirements are integral to administration of basic benefits.

As proposed, paragraph (f)(4) authorizes CMS, for 2022 and subsequent years, to set up to three MOOP limits using projections of beneficiary spending that are based on the most recent, complete Medicare FFS data. We would codify the current practice of setting the MOOP limits based on a percentile of projected Medicare FFS beneficiary out-of-pocket spending. Under this proposal, we would set up to three MOOP limits: The lower MOOP limit, the intermediate MOOP limit, and the mandatory MOOP limit. CMS uses these terms (lower, intermediate, and mandatory) in referencing MOOP limits instead of only ''voluntary'' and ''mandatory'' MOOP limits. As proposed, paragraph (f)(4) would also impose general rules for setting the MOOP limits. We are proposing to codify in § 422.100(f)(4)(ii) the current rule for using ranges to identify the type of MOOP limit an MA plan has established and applying that rule to the three types of MOOP limit. A mandatory MOOP limit is any dollar limit that is above the intermediate MOOP limit and at or below the mandatory MOOP limit threshold established each year. The intermediate MOOP limit is any dollar limit that is above the lower MOOP limit and at or below the intermediate MOOP limit threshold established each year. The lower MOOP limit is any dollar limit that is between $0.00 and up to and including the lower MOOP limit threshold established each year. As proposed in paragraph (f)(4)(iii), each MOOP limit would be rounded to the nearest whole $50 increment. Further, in cases where the MOOP limit is projected to be exactly in between two $50 increments, CMS would round to the lower $50 increment (for example, $7,125 would be rounded to $7,100) to protect beneficiaries from higher increases in costs by rounding down whenever possible.

We propose to codify in paragraphs § 422.100(f)(4)(iv), (v), and (vi) the rules for establishing the MOOP limits for contract year 2022, 2023, 2024, and for 2025 and subsequent years. In effect, the MOOP limits for contract year 2022 would be a recalibration of the MA MOOP limits to using a methodology that is adjusted from current practice. For contract year 2022, we propose to set the MOOP limits as follows:

(A) The mandatory MOOP limit is set at the 95th percentile of projected

Medicare FFS beneficiary out-of-pocket spending.

(B) The intermediate MOOP is set at the numeric midpoint of mandatory and lower MOOP limits.

(C) The lower MOOP limit is set at the 85th percentile of projected Medicare FFS beneficiary out-of-pocket spending.

These MOOP limits would be set subject to the rounding rules in paragraph (f)(4)(iii). Under our proposal, CMS would use projections for the applicable contract year of out-of-pocket expenditures for Medicare FFS beneficiaries that are based on the most recent, complete Medicare FFS data that incorporates a percentage of the costs incurred by beneficiaries with diagnoses of ESRD, using the ESRD cost transition schedule proposed in paragraph (f)(4)(vii). We explain in detail that transition schedule and the data we propose to use for setting MOOP limits later in this section of the proposed rule.

For future contract years, we propose to set the MOOP limits using a methodology that takes into account the amount of change from the prior year's MOOP limits in a way that minimizes disruption and change for enrollees and plans. Our proposed methodology is designed to allow plans to provide stable benefit packages year over year by minimizing MOOP limit fluctuations unless a consistent pattern of increasing or decreasing costs emerges over time. Again, these MOOP limits would be set subject to the rounding rules and using projections based on the most recent, complete Medicare FFS data that incorporates a percentage of the costs incurred by beneficiaries with diagnoses of ESRD, using the transition schedule in paragraph (f)(4)(vii).

To set the mandatory and lower MOOP limits for contract years 2023 and 2024 or, if later, until the end of the ESRD cost transition we would follow these steps:

- Review OACT projections of out-of-pocket spending for the applicable year that is based on updated Medicare FFS data, including all spending regardless of ESRD diagnoses;
- Compare the applicable year's projection of the 95th percentile and 85th percentiles to the prior year's projections;
- Determine if the prior year's projection for the 95th percentile and 85th percentile are within a range, above or below, of two percentiles of the applicable percentile in that updatedprojection. For example, for the contract year 2023 mandatory MOOP limit, we would determine if the contract year 2022 95th percentile projection is between or equal to the 93rd and 97th percentiles of the projections for 2023 out-of-pocket expenditures;
- If the prior year's 95th and 85th percentile projections are between or equal to the two percentile range above or below, we would continue the ESRD cost transition schedule proposed in paragraph (f)(4)(vii) for one or both of the MOOP limits;
- If one or both of the prior year's 95th and 85th percentile projections are not within that range, we would increase or decrease one or both of the MOOP limits up to 10 percent of the prior year's MOOP limit annually until the MOOP limit reaches the projected 95th percentile for the applicable year, subject to the rounding rules as proposed in paragraph (f)(4)(iii). For example, if the dollar amount needed to be transitioned represents 15 percent, then 10 percent would be addressed during the first year, while any remaining amount would be addressed during the second year, if applicable based on updated data projections from the OACT. During this period of time we would delay implementation of the next step in the ESRD cost transition schedule proposed in paragraph (f)(4)(vii). The ESRD cost transition schedule would resume at the rate that was scheduled to occur once the prior year's projected 95th and 85th percentile remains within the range of two percentiles above or below the projected 95th percentile for the upcoming contract year. For example, for the contract year 2023 mandatory MOOP limit, if the 2023 projected 95th percentile corresponds to the projected 98th percentile for contract year 2022 out-of-pocket expenditures, we would set the contract year 2023 mandatory MOOP by: Increasing the contract year 2022 mandatory MOOP limit by up to 10 percent and rounding as proposed in paragraph (f)(4)(iii); and
- The intermediate MOOP limit would be set by either maintaining it as the prior year's intermediate MOOP limit (if the mandatory and lower MOOP limits are not changed) or updating it to the new numerical midpoint of the mandatory and lower MOOP limits, and rounding as proposed in paragraph (f)(4)(iii). We propose regulation text to implement this process for setting the mandatory, intermediate, and lower MOOP limits at § 422.100(f)(4)(v), with paragraphs (f)(4)(v)(A), (B) and (C) addressing the mandatory, intermediate, and lower MOOP limits respectively.

For contract year 2025 or following the ESRD cost transition schedule proposed in paragraph (f)(4)(vii) and for subsequent years, we propose to include in the methodology a means to take into account trends that are consistent for three years. The proposed regulation text includes ''or following the ESRD cost transition'' to clarify that the ESRD cost transition schedule may end in 2025 or extend longer due to our proposals for how we would handle any sudden increases or decreases in costs. For example, if for contract year 2023, the projected 95th percentile amount represents the 98th percentile from the prior year's (contract year 2022) projections, then we would only increase the MOOP limit for contract year 2023 by up to 10 percent of the prior year's MOOP amount and extend the ESRD cost transition schedule past 2025 by the number of years it takes until the upcoming year's projected 95th percentile amount was within two percentiles above or below the prior year's projection of the 95th percentile. We propose the methodology for the mandatory and lower MOOP limits for contract year 2025 or following the ESRD cost transition schedule as follows: the prior year's corresponding MOOP limit is maintained for the upcoming contract year if: (1) The prior year's MOOP limit amount is within the range of two percentiles above or below the projected 95th or 85th percentile of Medicare FFS beneficiary out-of-pocket spending incurred by beneficiaries with and without diagnoses of ESRD and (2) the projected 95th or 85th percentile did not increase or decrease for three consecutive years in a row. If the prior year's corresponding MOOP limit is not maintained because either (1) or (2) occur, CMS increases or decreases the MOOP limit by up to 10 percent of the prior year's MOOP amount annually until the MOOP limit reaches the projected applicable percentile for the applicable year, based on the most recent, complete data projections from the OACT. The intermediate MOOP limit would be set by either maintaining it as the prior year's intermediate MOOP limit (if the mandatory and lower MOOPs are not changed) or updating it to the new numerical midpoint of the mandatory and lower MOOP limits, and rounding as proposed in paragraph (f)(4)(iii). We propose regulation text to implement this process for setting the mandatory, intermediate, and lower MOOP limits for contract year 2025 or following the data transition schedule and subsequent years at § 422.100(f)(4)(vi), with paragraphs (f)(4)(vi)(A), (B), and (C) addressing the mandatory, intermediate, and lower MOOP limits respectively.

This approach aims to allow plans to provide stable benefit packages year over year by minimizing MOOP limit

fluctuations unless a consistent pattern of increasing or decreasing costs emerges over time. We solicit comment on this approach in light of our goal of avoiding enrollee confusion and maintaining stable benefit packages. We also solicit comments whether our proposed regulation text adequately and clearly specifies the methodology that will be used to set the MOOP limits each year. We intend to issue annual guidance applying these rules, sufficiently in advance of the bid deadline so that MA organizations know and understand the MOOP limits for the upcoming year.

We would continue the current policy of setting the combined MOOP limits (that is, the MOOP limits that cover in-network and out-of-network benefits) for PPOs by multiplying the respective in-network MOOP limits by 1.5 for the relevant year and rounding as proposed in paragraph (f)(4)(iii) if necessary. We propose to codify this rule for MA regional plans in § 422.101(d)(3) and to cross-reference that rule for MA local PPOs in § 422.100(f)(5)(i).

Because of the change in eligibility requirements for MA plans regarding beneficiaries with diagnoses of ESRD, we believe that it is appropriate that the data we use to set the MOOP limits also reflect the out-of-pocket expenditures of such beneficiaries. We therefore propose to codify rules for what data CMS would use to set the MOOP limits that are consistent with current practice, but revised to take into account costs incurred by beneficiaries with diagnoses of ESRD. CMS currently sets MOOP limits using projected Medicare FFS beneficiary out-of-pocket spending for the upcoming year, which are based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Medicare FFS, excluding all costs for beneficiaries with ESRD. For example, for contract year 2020 MOOP limits, we used projected out-of-pocket costs for Medicare FFS beneficiaries (excluding out-of-pocket costs from beneficiaries with diagnoses of ESRD) from the OACT, based on the most recent complete Medicare data (from 2018). We excluded the costs for individuals with diagnoses of ESRD because of the limits on when and how a Medicare beneficiary with diagnoses of ESRD could enroll in an MA plan under section 1851(a) of the Act. Under the current enrollment limitations, in contract year 2018, 0.6 percent of the MA enrollee population, or approximately 121,000 beneficiaries, have diagnoses of ESRD, using CMS data.[69]

As discussed in section IV.A. of this proposed rule, section 1851(a)(3) of the Act, as amended by the Cures Act, will allow Medicare beneficiaries with diagnoses of ESRD to enroll in MA plans beyond current enrollment limitations, beginning in contract year 2021. CMS expects this change will result in Medicare beneficiaries with diagnoses of ESRD to begin transitioning to or choosing MA plans in greater numbers than what has happened so far (in light of the prior limitations under section 1851(a) of the Act). To ensure that the MOOP limits take into account out-of-pocket costs for beneficiaries with diagnoses of ESRD, we propose a multi-year transition from our current practice of excluding all costs incurred by beneficiaries with diagnoses of ESRD to including all related costs into the Medicare FFS data that is used to set the MOOP limits. We propose to codify the transition schedule at § 422.100(f)(4)(vii).

We propose to factor in a percentage of the difference between the projected costs that are based on, first, data for beneficiaries without diagnoses of ESRD and second, based on data that includes beneficiaries with diagnoses of ESRD. We propose to use the term ''ESRD cost differential'' to refer to the difference between: (1) Projected out-of-pocket costs for beneficiaries using Medicare FFS data excluding the costs incurred by beneficiaries with ESRD diagnoses for contract year 2021 and (2) the projected out-of-pocket costs for all beneficiaries using Medicare FFS data (including the costs incurred by beneficiaries with ESRD diagnoses) for each year of the ESRD cost transition. We propose a specific schedule for factoring in a percentage of the ESRD cost differential annually until 2024 or, if later, the final year of the transition and beyond. As shown in Table 11, for MOOP limits for years after contract year 2022, CMS proposes to incorporate an additional 20 percent of the ESRD cost differential, as it is updated calculated each year using the most recent, complete data projections from the OACT, until contract year 2024 or the final year of transition. Table 11 shows MOOP limits calculated following these proposed rules and transition schedule, but using the data available at this time, to illustrate the impact of factoring in greater portions of the ESRD cost differential. In the final year of the transition, 100 percent of the costs incurred by beneficiaries with diagnoses of ESRD would be integrated into the most recent, complete Medicare FFS data that is used to project and determine MOOP limits.

For the 2021 contract year, the projected costs incurred by beneficiaries without ESRD diagnoses for the 95th percentile is $7,175 and for the 85th percentile is $3,360. Each year, we would compare the 95th and 85th percentiles of the projected out-of-pocket costs for all Medicare FFS beneficiaries for the upcoming year to these dollar amounts to calculate the ESRD cost differential for that year. We therefore propose to identify these dollar amounts in the regulation text defining the ESRD cost differential. Using the most recent, complete Medicare FFS data without costs incurred by beneficiaries with diagnoses of ESRD, the 95th percentile is projected to be $7,175 in contract year 2021, compared to $8,174 with related ESRD costs, a difference of $999. This is the same type of comparison we will complete each year based on complete and updated data projections provided by the OACT. Table 11 illustrates the MOOP limits set using these proposed rules and is based on projections using 2018 data. For example, for the 2022 contract year, we would take 60% of the ESRD cost differential ($599.40) and add it to the projected 95th percentile without ESRD costs to align with the proposed transition schedule, which equals $7,774.40. This rounds to $7,750; this means the mandatory MOOP limit range would be $5,601 (because the intermediate MOOP would be $5,600) through $7,750, as reflected in Table 11.

CMS developed this approach in consultation with the OACT to take into account the likely increase in enrollment of beneficiaries with diagnoses of ESRD in MA while ensuring that there is not a significant and sudden shift in the MOOP limits in any given year. CMS and the OACT do not expect 100 percent of Medicare beneficiaries with diagnoses of ESRD will enroll in the MA program immediately after the current enrollment limitations are lifted and as such, CMS is not proposing to integrate 100 percent of the costs within one contract year. Our goal is to strike a balance between potential increases in plan costs and enrollee cost sharing or premiums by scheduling adjustments to the MOOP limits to reflect a reasonable transition of ESRD beneficiaries into the MA program. Further, using a scheduled transition will allow MA organizations to plan for the change and mitigate sudden changes in MOOP limits, benefit

[69] *See page 14 from the 2020 Rate Notice and Final Call Letter, retrieved from https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

designs, and premiums that could be disruptive to enrollees and MA organizations. CMS's goal in the MOOP and Cost Sharing proposals in this proposed rule is to provide predictable and transparent MOOP limit and cost sharing standards and to set limits at a level that should not result in significant new costs for MA plans or enrollees. We solicit comment on whether the transition schedule proposed at 422.100(f)(4)(vii) aligns best to this goal or if the transition should be structured differently in terms of annual percentage of ESRD cost differential transition (for example, 50 percent in 2022, 70 percent in 2023 or, if later, the next year of transition, and 100 percent in the final year of transition).

Using the most recent, complete Medicare FFS data available at this time (2018 data), the OACT projected the out-of-pocket costs for Medicare FFS beneficiaries. CMS developed Table 4 for illustrative purposes to show how the most recently available projections of the 95th and 85th percentiles along with our proposed methodology results in mandatory, intermediate, and lower MOOP limits for in-network basic benefits for contract years 2022 through 2024. CMS also developed Table 5 to show the current projections of combined MOOP limits for in-network and out-of-network basic benefits based on our proposed methodology (that is, multiplying the respective in-network MOOP limits by 1.5 for the relevant year). Overall, Table 4 and Table 5 illustrate examples of potential MOOP limits that integrate the ESRD cost differential over multiple years (60 percent by 2022, 80 percent for 2023 or, if later, the next year of transition, and 100 percent for 2024 or the final year of transition) and include application of the rounding rules as proposed in paragraph (f)(4)(iii). These are only illustrative MOOP limits for contract years 2022 through 2024 to show the potential impact of our proposal for incorporating the out-of-pocket costs of FFS beneficiaries with diagnoses of ESRD into the most recent, complete Medicare FFS data we currently have to set the MOOP limits. We expect these numbers will change when we receive the next year's projections from the OACT and CMS will update the MOOP limits using the methodology decided upon in the final rule. We intend to apply the revised regulations each year to calculate the MOOP limits and to publish the annual MOOP limits with a description of how the regulation standard is applied (that is, the methodology used) through Health Plan Management System (HPMS) memoranda issued prior to bid submission each year.

TABLE 4—ILLUSTRATIVE EXAMPLE OF IN-NETWORK MOOP LIMITS BASED ON MOST RECENT MEDICARE FFS DATA PROJECTIONS

MOOP limit	Approximate original Medicare percentile	Contract year 2022	Contract year 2023	Contract year 2024
Mandatory	95t	$5,601 to $7,750	$5,701 to $7,950	$5,801 to $8,150.
Intermediate	Approximate numeric midpoint*	$3,451 to $5,600	$3,501 to $5,700	$3,501 to $5,800.
Lower	85th	$0 to $3,450	$0 to $3,500	$0 to $3,500.

*The intermediate MOOP limit would be based on the mandatory MOOP limit, less approximately 50 percent of the numeric difference between the mandatory and lower MOOP limits.

TABLE 5—ILLUSTRATIVE EXAMPLE OF COMBINED MOOP LIMITS FOR LPPO AND CATASTROPHIC (MOOP) LIMITS FOR RPPO PLANS BASED ON MOST RECENT MEDICARE FFS DATA PROJECTIONS

MOOP limit*	Contract year 2022	Contract year 2023	Contract year 2024
Mandatory	$8,401 to $11,600	$8,551 to $11,900	$8,701 to $12,200.
Intermediate	$5,151 to $8,400	$5,251 to $8,550	$5,251 to $8,700.
Lower	$0 to $5,150	$0 to $5,250	$0 to $5,250.

*Combined MOOP limits are calculated by multiplying the respective MOOP limits by 1.5 for the relevant year.

Under our proposal, we intend to explain how we apply the methodology we have proposed to codify at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) and the resulting MOOP limits for each year on a timely basis through HPMS memoranda. We solicit comment whether we should codify a specific rule requiring CMS to issue such subregulatory guidance applying the methodology in these regulations by a specific date each year.

CMS also seeks comments and suggestions on whether additional regulation text or restructuring of §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) is needed to achieve CMS's goal of providing additional transparency on how CMS will: (1) Set up to three in-network and out-of-network MOOP limits for local and regional MA plans; (2) transition ESRD costs into MOOP limit calculations; and (3) calculate MOOP limits during and after completion of the transition of data about cost sharing expenses for beneficiaries with diagnoses of ESRD.

B. Service Category Cost Sharing Limits for Medicare Parts A and B Services and per Member per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113)

Section 1852 of the Act imposes a number of requirements that apply to the cost sharing and benefit design of MA plans. First, section 1852(a)(1)(B) of the Act provides that the MA organization must cover the benefits under Parts A and B (that is, basic benefits as defined in § 422.100(c)) with cost sharing that is the same or at least actuarially equivalent to cost sharing in original Medicare; this is repeated in a bid requirement under section 1854(e)(4) of the Act. We have addressed and implemented that requirement in several regulations, including §§ 422.101(e), 422.102(a)(4), and 422.254(b)(4). Second, section 1852(a)(1)(B) of the Act also imposes particular constraints on the cost sharing for specific benefits, which have been implemented in § 422.100(j) for MA plans and extended to cost plans under § 417.454(e); the statute explicitly authorizes CMS to add to the list of items and services for which MA cost sharing may not exceed the cost sharing levels in original Medicare. Third, section 1852(b)(1) of the Act prohibits discrimination by MA organizations on

the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals. The requirements under §§ 422.100(f)(4) and (5) that impose MOOP limits on local MA plans are based on this anti-discrimination provision and align with the statutory catastrophic limits imposed on regional MA plans under section 1858(b) of the Act. Section 422.100(f)(6) provides that cost sharing must not be discriminatory and CMS has issued guidance addressing discriminatory cost sharing, as applied to specific benefits and to categories of benefits, in the annual Call Letter and in Chapter 4 of the Medicare Managed Care Manual (MMCM) under this regulation. Establishing limits on cost sharing for covered services is an important way to ensure that the cost sharing aspect of a plan design does not discriminate against or discourage enrollment in an MA plan by beneficiaries who have high health care needs.

Currently, CMS annually analyzes Medicare program data to interpret and apply the various cost sharing limits from these authorities and to publish guidance on MA cost sharing limits in the annual Call Letter. The relevant Medicare data includes the most recent, complete Medicare FFS data, including cost and utilization data and MA patient utilization information from MA encounter data. CMS sets cost sharing limits based on analyses of and projections from this data and then reviews cost sharing established by MA organizations to determine compliance with the cost sharing limits and requirements established in the statute and regulations, as interpreted and implemented in sub-regulatory guidance, including Chapter 4 from the MMCM. The cost sharing limits set by CMS reflect a combination of outpatient visits and inpatient utilization scenarios based on length of stays typically used by average to sicker patients. CMS uses multiple inpatient utilization scenarios to guard against MA organizations setting inpatient cost sharing amounts in a manner that is potentially discriminatory. Review parameters are also established for frequently used professional services, such as primary and specialty care services. We are proposing to codify our current (and in many cases, long-standing) practice and methodology for interpreting and applying the limits on MA cost sharing, with some modifications.

In using the most recent, complete Medicare FFS data for developing and applying the reviews of MA cost sharing, CMS excludes the costs for individuals with diagnoses of ESRD because of the current restrictions on when and how a Medicare beneficiary with diagnoses of ESRD could enroll in an MA plan under section 1851(a) of the Act. In contract year 2018, 0.6 percent of the MA enrollee population, or approximately 121,000 beneficiaries, have ESRD based on the statutory definition and CMS data.[70] As discussed in more detail in section IV.A. of this proposed rule, section 17006 of the Cures Act has amended the Medicare statute to allow Medicare beneficiaries with diagnoses of ESRD to enroll in MA plans beginning in contract year 2021. CMS expects this change will result in Medicare beneficiaries with diagnoses of ESRD beginning to transition to, or choosing, MA plans in greater numbers than they do currently, but the rate of transition is currently unknown. Given the potential increase in enrollment of beneficiaries with diagnoses of ESRD in MA, the OACT has conducted an analysis to determine the impact of including all costs incurred by beneficiaries with diagnoses of ESRD into the most recent, complete Medicare FFS data CMS uses to project future out-of-pocket expenditures to establish cost sharing standards and limits. Based on the most recent analyses and projections, adding in ESRD costs affects MA cost sharing limits for inpatient hospital acute length of stay scenarios, with the longer length of stay scenarios being the most affected. As discussed in section VI.A. of this proposed rule, CMS is proposing, at § 422.100(f)(4)(vii), a schedule for incorporating use of the most recent, complete Medicare FFS data for beneficiaries with diagnoses of ESRD into the data used to set MOOP limits. The proposal here to codify, with some updates and changes, the current process for establishing non-discriminatory cost sharing limits similarly takes into account data about out-of-pocket expenditures for beneficiaries with diagnoses of ESRD. In addition, CMS is proposing to provide additional transparency on how updates are made to inpatient hospital acute and psychiatric length of stay scenarios in conjunction with the ESRD cost transition, as described in the 2020 Final Call Letter for contract year 2021. CMS also proposes to codify the methodology used to set the standards for MA cost sharing for professional services and for inpatient hospital acute and psychiatric services at § 422.100(f)(6). Under our proposal, an MA plan must have cost sharing that does not exceed the standards set each year using the methodology in paragraph (f)(6). The limits in proposed § 422.100(f)(6) would be in addition to other limits on cost sharing that apply to MA plans. We are also proposing, at § 422.100(j), that MA plans must not impose cost sharing that exceeds original Medicare for certain specific benefits and for certain categories of benefits on a per member per month actuarially equivalent basis. Our proposal would also set specific cost sharing requirements for emergency services (including post-stabilization service) and urgently needed services, which would be codified in § 422.113(b)(2)(v) and (vi).

CMS is committed to encouraging plan offerings with more favorable MOOP and cost sharing limits. Accordingly, CMS is proposing to modify the regulations at §§ 422.100(f)(6) and 422.113(b)(2)(v) and (vi) to establish a range of cost sharing limits for benefits furnished on an in-network basis based on the MOOP limit established by the MA plan. Increasing the flexibility MA organizations have in setting cost sharing limits based on more favorable MOOP limits should incentivize more favorable benefit designs for MA enrollees.

In addition, this proposal for amending §§ 422.100(f)(6) and (j) and 422.113(b)(2) implements safeguards to ensure MA enrollees are not subject to discriminatory benefits or discriminatory costs for basic benefits. These safeguards include codifying a longstanding interpretation of the current anti-discrimination provision that payment of less than 50 percent of the total MA plan financial liability discriminates against enrollees who need those services. Specifically, CMS proposes to codify at § 422.100(f)(6)(i)(A) that MA plans may not pay less than 50 percent of the total MA plan financial liability, regardless of the MOOP limit established, for basic benefits that are provided in-network and out-of-network that are not explicitly proposed in the cost sharing standards at § 422.100(f)(6). This proposal as a whole, in combination with the MOOP proposal in section VI.A. of this proposed rule, aims to provide MA organizations incentives to offer plans with favorable benefit designs for beneficiaries. Under sections 1854(a)(1)(A) and 1860D–11(b) of the Act, initial bid submissions for all MA organizations are due the first Monday

[70] *See page 14 from the 2020 Rate Notice and Final Call Letter, retrieved from https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

in June and shall be in a form and manner specified by the Secretary. Organizations may design their plan benefits as they see fit so long as they satisfy Medicare coverage requirements, including applicable MA regulations. MA organizations typically offer benefits with lower cost sharing amounts than the limits published in the annual Call Letter; we believe this is due to multiple factors, including the principles and incentives inherent in managed care, effective negotiations between organizations and providers, and competition. CMS also reminds organizations that they also must comply with applicable Federal civil rights laws that prohibit discrimination on the basis of race, national origin, gender, disability, chronic disease, health status, or other prohibited basis including section 1557 of the Affordable Care Act, title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975. None of the proposed regulations under this rule limit application of such anti-discrimination requirements.

1. General Non-Discriminatory Cost Sharing Limits (§§ 422.100(f)(6))

We are proposing to codify in § 422.100(f)(6) a set of general rules for cost sharing for basic benefits. We use the term ''basic benefits'' as defined in § 422.100(c) to mean items and services (other than hospice care and, beginning 2021, coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B of Medicare, including additional telehealth benefits offered consistent with the requirements at § 422.135. Under our proposal, the rules in § 422.100(f)(6) must be followed by MA plans in addition to other regulatory and statutory requirements for cost sharing. MA organizations have the option to charge either coinsurance or a copayment for most benefit category benefits, which the proposed regulation text makes clear. Under our proposal, the MA plan cannot exceed the coinsurance or copayment limit for benefit category standards established by CMS using the various rules in the regulation.

We are proposing to codify our longstanding interpretation of the anti-discrimination provisions that payment of less than 50 percent of the total MA plan financial liability discriminates against enrollees who have high health needs and discourages enrollment in the plan by such beneficiaries. We recognize that it is difficult to set a cost sharing limit for every possible benefit and believe that this catch-all rule, which has been longstanding policy used in our review of bids, is an important beneficiary protection. This rule would apply regardless of the MOOP limit established and regardless whether the basic benefit is furnished in-network or out-of-network, to protect beneficiaries regardless of the MA plan or MOOP limit they choose. As used in the proposed regulation text, the term ''total MA plan financial liability'' means the total payment paid and includes both the enrollee cost sharing and the MA organization's payment. Specifically, CMS proposes to codify at § 422.100(f)(6)(i) that MA plans may not pay less than 50 percent of the total MA plan financial liability, regardless of the MOOP limit established, for in-network benefits and out-of-network benefits for which a cost sharing limit is not otherwise specified in proposed paragraph (f)(6), inclusive of basic benefits. In order to clarify this policy, we are also proposing in paragraphs (f)(6)(i)(B) and (C) how this rule would apply when coinsurance or copayment structures are used. Under our proposal, if the MA plan uses copayments, the copayment for an out-of-network benefit cannot exceed 50 percent of the average Medicare FFS allowable cost for that service area and the copayment for in-network benefits cannot exceed 50 percent of the average contracted rate of that benefit (item or service); if the MA plan uses coinsurance, then the coinsurance cannot exceed 50 percent.

We are also proposing general rules to govern how CMS would set copayment limits under this proposal. Proposed paragraph (f)(6)(ii)(A) provides that CMS rounds to the nearest whole $5 increment for professional services and nearest whole $1 for inpatient acute and psychiatric and skilled nursing facility cost sharing limits. Proposed paragraph (f)(6)(B) provides that for all cases in which the copayment limit is projected to be exactly between two increments, CMS rounds to the lower dollar amount. This rounding rule codifies for the most part current policy but with slight modification to protect beneficiaries from higher increases in costs by rounding down whenever possible.

In proposed paragraph (f)(6)(iii), we would codify rules to give MA plans flexibility in setting cost sharing for professional services, including primary care services, physician specialist services, partial hospitalization, and rehabilitation services. The proposed flexibility is in many respects the same as the flexibility we currently provide for MA plans that use the lower, voluntary MOOP limit, but with modifications to account for our proposal to set up to three MOOP limits each year. Proposed new § 422.100(f)(6)(iii)(A) provides that an MA plan may not establish cost sharing that exceeds the limits set under paragraph (f)(6)(iii) for basic benefits that are professional services furnished in-network (that is, by contracted providers). Proposed new § 422.100(f)(6)(iii)(B) specifies the data that CMS would use in applying the methodology in paragraph (f)(6)(iii) to set the cost sharing limits: Projections of out-of-pocket costs representing beneficiaries with and without diagnoses of ESRD based on the most recent, complete Medicare FFS data for basic benefits that are professional services. Proposed new § 422.100(f)(6)(iii)(C) outlines the method for setting the cost sharing limits for professional services each year and clarifies that the resulting limits (specified as dollar amounts) are subject to the rounding rules in paragraph (f)(6)(ii). The cost sharing limits would vary based on the type of MOOP limit used by the MA plan and would be as follows:

(1) Mandatory MOOP limit: 30 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 70 percent of the total MA plan financial liability.

(2) Intermediate MOOP limit: 40 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 60 percent of the total MA plan financial liability.

(3) Lower MOOP limit: 50 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 50 percent of the total MA plan financial liability. We are proposing that the MA plan must pay a specific percentage of the total financial liability for professional services to align with the range of flexibility each MOOP limit provides. By specifying this in regulation, we are ensuring that there is a clear increase in MA organization financial responsibility for professional services if they choose a mandatory MOOP limit rather than a lower or intermediate MOOP limit. We arrived at the specified percentages discussed previously by assigning the highest coinsurance amount that was not discriminatory (50%) to the lowest MOOP limit; and 30% coinsurance (which is most closely related to limits stated in the CY 2020 Call Letter) to the mandatory MOOP limit, to balance the beneficiary incentives for each type of MOOP limit. Then, we established the midpoint (40%) for the intermediate MOOP limit. These coinsurance percentages also result in reasonable differences between expected copayment limits for each of the MOOP

limits. Overall, we aim to prevent discrimination by setting these limits to serve as caps to how much financial responsibility the MA organization can transfer to enrollees for professional services. Accordingly, 422.100(f)(6) clarifies that MA organizations cannot disproportionally increase cost sharing for specific benefit categories beyond the specified percentages. To set the actuarially equivalent values each year, CMS would work with the OACT to establish copayment limits that are approximately equal to the identified coinsurance percentage limit based on projections of the most recent, complete Medicare FFS data that includes 100 percent of the out-of-pocket costs representing all beneficiaries with and without diagnoses of ESRD.

We propose to base the approximate actuarially equivalent copayment limits for primary care, physician specialties, mental health specialty services, and physical and speech therapy on the most recent, complete Medicare FFS average cost data (including 100 percent of the out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD), weighted by utilization by the applicable provider specialty types for each service category. We believe that using an average that is weighted by specialty type utilization is consistent with developing the actuarially equivalent copayment for the coinsurance percentage specified in proposed § 422.100(f)(6)(iii). We solicit comment on whether our regulation text should be further revised on this point. The applicable provider specialty types include:

A. Primary Care: Family Practice; General Practice; Internal Medicine
B. Physician Specialties: Cardiology; Geriatrics; Gastroenterology; Nephrology; Otolaryngology (ENT)
C. Mental Health Specialty Services: Clinical Psychologist; Licensed Clinical Social Worker; Psychiatry
D. Physical and Speech Therapy: Physical Medicine and Rehabilitation; Speech-language Pathologists

We propose to base the approximate actuarially equivalent copayment limits for psychiatric services, occupational therapy, and chiropractic care on the most recent, complete Medicare FFS cost data from a single, most applicable provider specialty. Respectively, this includes Psychiatry, Occupational Therapist, and Chiropractor. We solicit comment on whether other provider specialty types should inform our proposed actuarially equivalent copayment limits for the various professional services. We direct readers to Table 4 for an illustration of how cost sharing limits would be developed based on the most recent, complete data projected to the applicable contract year for professional services, emergency services/post stabilization care, and urgent care.

CMS issued guidance in Chapter 4, section 50.1 ''Guidance on Acceptable Cost-sharing'' of the MMCM that cost sharing should appear to MA enrollees consistent with MA disclosure requirements at § 422.111(b)(2). Section 422.111(b)(2) requires MA plans to clearly and accurately disclose benefits and cost sharing. Accordingly, MA plans must identify (and charge) the enrollee's entire cost sharing responsibility as a single copay (if using copayment rather than coinsurance) even if the MA plan has differential cost sharing that varies by facility setting or contracted arrangements that involves separate payments to facilities (or settings) and providers. We are aware of situations where a facility or setting charges a separate amount from the health care provider that actually furnishes covered services, such as an emergency department fee and a fee for the emergency room physician. In such situations, those fees should be combined (bundled) into the cost sharing amount for that particular place of service and be clearly reflected as a total copayment in appropriate materials distributed to beneficiaries. We believe that this current guidance is an appropriate interpretation of § 422.111 but solicit comment on whether the existing regulations are sufficiently clear or if clarification in the regulation text would be helpful to avoid potential confusion on how MA plans should bundle copayments.

2. Cost Sharing Limits for Inpatient Hospital Acute and Psychiatric Services (§ 422.100(f)(6)(iv))

Since contract year 2011, CMS has annually announced the maximum cost sharing permitted for inpatient length of stay scenarios for both acute and psychiatric care. For each length of stay scenario, CMS set cost sharing limits based on a percentage of estimated Medicare FFS cost sharing projected to the applicable contract year. The OACT conducts an annual analysis of the most recent, complete Medicare FFS data, and uses that data to project costs for the Part A deductible and Part B costs based on the length of stay scenarios and the setting of the inpatient stay (acute or psychiatric), to help determine the inpatient hospital acute and psychiatric cost sharing limit amounts. CMS compares the cost sharing for an MA enrollee under the plan design for each bid to the projected Medicare FFS cost sharing in each scenario; for MA plans with the mandatory MOOP limit, the cost sharing limit is 100 percent of the Medicare FFS cost sharing for the applicable scenario and for MA plans using the lower, voluntary MOOP limit, it is 125 percent of the Medicare FFS cost sharing. If an MA plan's cost sharing exceeds the applicable limit for any of the length of stay scenarios, CMS considers the MA plans' cost sharing as discriminatory under current § 422.100. We are proposing new § 422.100(f)(6)(iv)(A) through (D) to codify this longstanding policy for the cost sharing established by an MA plan for inpatient acute and psychiatric services, with modifications to take into account cost sharing expenditures for beneficiaries with diagnoses of ESRD in setting the limits and to set a limit for MA plans that use the intermediate MOOP limit. Under proposed paragraph (f)(6)(iv)(A), an MA plan is required to have cost sharing for inpatient acute and psychiatric benefits that do not exceed the limits set in § 422.100(f)(6)(iv). Our proposal aims to provide transparency on how CMS will set the thresholds with which MA cost sharing must comply for inpatient hospital acute and psychiatric benefits. In reviewing bids, we will evaluate MA cost sharing to determine whether it complies with the limits set under this proposed new regulation text.

We propose that the cost sharing limits are set for each of the seven inpatient stay scenarios for which cost sharing would apply under original Medicare. The inpatient hospital acute stay scenarios are for 3 days, 6 days, 10 days, and 60 days and the psychiatric inpatient hospital stay scenarios are for 8 days, 15 days, and 60 days. Most of these are the same scenarios used in the contract year 2020 Call Letter and in previous years. Cost sharing limits for each of the seven inpatient hospital length of stay scenarios incorporates the estimated Medicare FFS inpatient Part A deductible and Part B professional costs. Plans may vary cost sharing for different admitting health conditions, providers, or services provided, but overall benefit cost sharing must satisfy the limits established by CMS. We identify these length of stay scenarios in proposed paragraph (f)(6)(iv)(B). Proposed paragraph (f)(6)(iv)(C) describes the data CMS would use for establishing the Medicare FFS out-of-pocket costs for each scenario. CMS would use projected out-of-pocket costs and utilization data based on the most recent, complete Medicare FFS data that factors in out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD

on the transition schedule described in paragraphs (f)(4)(vii)(A) through (D) and may also use patient utilization information from MA encounter data. For purposes of setting these cost sharing limits, the Medicare FFS data that factors in the ESRD cost differential would not include the exceptions for the MOOP limit calculations that are described at § 422.100(f)(4)(v)(A) and (C). In essence, the exceptions relate to how the ESRD cost transition would be delayed if the prior year's projected 95th or 85th percentile (including costs incurred by all Medicare FFS beneficiaries with and without diagnoses of ESRD) is two percentiles above or below the projected 95th or 85th percentile for the upcoming contract year. This exception is not relevant for setting inpatient cost sharing limits as our methodology does not utilize percentiles to establish length of stay scenario limits.

OACT conducted an analysis to help determine the impact of including all costs incurred by beneficiaries with diagnoses of ESRD into the most recent, complete Medicare FFS data used to establish cost sharing standards. This analysis found adding in related ESRD costs affects inpatient hospital acute cost sharing limits. For example, in contract year 2021 the inpatient hospital acute 60 day limit without ESRD costs for MA plans that establish a mandatory MOOP limit is projected to be $4,645 and with 100 percent of ESRD costs increases to $5,073. This is an increase of $428, due to increased Part B professional fees ($3,169 for 60 days without ESRD costs and $3,597 with 100 percent of ESRD costs). The projected Part A deductible of $1,476 stays the same in both calculations. Although costs incurred by beneficiaries with diagnoses of ESRD costs are not expected to impact inpatient hospital psychiatric standards based on current projections, we are proposing to update the methodology to consider ESRD costs for all inpatient hospital acute and psychiatric standards. Specifically, CMS proposes to integrate approximately 60 percent of the difference between Medicare FFS costs incurred by all beneficiaries (including those with diagnoses of ESRD) and the costs excluding beneficiaries with diagnoses of ESRD into the data used to set the inpatient hospital acute and psychiatric cost sharing limits for contract year 2022. After contract year 2022, CMS will incorporate an additional 20 percent of costs incurred by beneficiaries with diagnoses of ESRD each year until contract year 2024, when CMS will integrate 100 percent of the costs incurred by beneficiaries with diagnoses of ESRD into the most recent, complete Medicare FFS data that is used to determine inpatient hospital acute and psychiatric cost sharing limits. This is the same as the proposed transition schedule of ESRD costs into MOOP limit calculations discussed in section VI.A. of this proposed rule. Accordingly, we cross-reference that transition at § 422.100(f)(6)(iv)(C) to avoid repetitive regulation text.

We will apply the transition of ESRD costs across all existing and new inpatient hospital length of stay scenarios. Specifically, we propose to add a 3-day length of stay scenario for acute stays and an 8-day length of stay scenario for psychiatric care to the scenarios we have used for the past several years. The proposed 3-day and 8-day stay scenarios for inpatient hospital acute and psychiatric standards were determined based on Medicare FFS data and informed by patient utilization information from MA encounter data. For example, the analysis of Medicare FFS 2015–2017 claims data indicates that 3 days was the median length of stay within an inpatient hospital acute setting. CMS also reviewed patient utilization during the same 2015–2017 time period using MA encounter data and noted the median length of stay was about the same for MA enrollees. Based on the combined data, we believe the addition of a 3-day length of stay cost sharing limit is an appropriate addition to our existing inpatient hospital acute cost sharing standards (6 days, 10 days, and 60 days). CMS completed similar analyses regarding psychiatric stays and is, therefore, proposing to add an 8-day length of stay scenario to the existing psychiatric length of stay scenarios (15 days and 60 days) used in the past.

Finally, in paragraph (f)(6)(iv)(D), we are proposing specific cost sharing limits for inpatient acute and psychiatric stays that are tied to the type of MOOP limit used by the MA plan. These limits are stated as percentages of the FFS costs for each length of stay scenario:

(1) Mandatory MOOP limit: Cost sharing must not exceed 100 percent of estimated Medicare Fee-for-Service cost sharing, including the Part A deductible and related Part B costs.

(2) Intermediate MOOP limit: Cost sharing must not exceed the numeric mid-point between the cost sharing limits for the mandatory and lower MOOP limits.

(3) Lower MOOP limit: Cost sharing must not exceed 125 percent of estimated Medicare Fee-for-Service cost sharing, including the Part A deductible and related Part B costs. Consistent with existing policy, for inpatient acute 60 day length of stays, MA plans that establish a lower MOOP limit have the flexibility to set cost sharing above 125 percent of estimated Medicare Fee-for-Service cost sharing as long as the total cost sharing for the inpatient benefit does not exceed the MOOP limit or cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis.

This proposal would continue the established percentage of estimated Medicare FFS cost sharing for the mandatory and lower MOOP limits (100 percent and 125 percent respectively) to determine inpatient hospital acute and psychiatric cost sharing limits. Using the rule proposed for paragraph (f)(6)(ii)(A), all inpatient hospital acute and psychiatric cost sharing limits would be rounded to the nearest or lower whole $1 increment. Our proposal for limits on the cost sharing an MA plan uses for inpatient acute and psychiatric services aligns with our current practice (with some modifications, as discussed) and will provide benefit design stability for MA plans. CMS would continue to publish acceptable inpatient hospital acute and psychiatric cost sharing limits and a description of how the regulation standard is applied (that is, the methodology used) through subregulatory means, such as Health Plan Management System (HPMS) memoranda, issued prior to bid submission each year.

Table 4 is based on the most recent, complete Medicare FFS data available and then projected to contract years 2022 through 2024 to provide an illustrative example of how CMS would apply our proposals related to inpatient hospital acute standards for the 10-day length of stay scenario. As such, the limits for contract years 2022 through 2024 in Table 4 are illustrations only. The actual cost sharing limits developed under the rules we are proposing would change each year as OACT will update Part A deductible, Part B professional costs, and Medicare FFS cost assumptions annually prior to bid submission; the actual cost sharing limits for these future years, applying the final rules, could increase or decrease accordingly. In developing Table 4, we calculated the proposed contract year 2022 inpatient hospital acute 10-day length of stay scenario cost sharing limit for a MA plan that establishes a mandatory MOOP limit ($2,242 in Table 4) as follows:

(i) Add the projected Part B professional costs per day, up to a 10-day inpatient acute hospital stay. The

first day Part B professional costs are $251.00, followed by, $77.00, $49.00, $47.00, $50.00, and $245.00 for the next five days combined. This totals to $719.00 for a 10-day stay, regardless of the health condition initiating the hospitalization.

(ii) Add the $719.00 subtotal of projected Part B professional costs to the projected Part A deductible ($1,476.00) which equals $2,195.00.

(iii) Add 60 percent of the ESRD cost differential ($46.80) to the sum of Part A and B costs ($2,195.00) which equals $2,241.80.

(iv) Round that sum ($2,241.80) to the nearest whole dollar which equals, $2,242.00.

TABLE 4—ILLUSTRATIVE EXAMPLE OF COST SHARING LIMITS BASED ON CURRENT MEDICARE FFS DATA FOR INPATIENT HOSPITAL ACUTE 10-DAY LENGTH OF STAY SCENARIO

MOOP limit	Percent of estimated medicare FFS cost sharing	Contract year 2022	Contract year 2023	Contract year 2024
Mandatory	100	$2,242	$2,257	$2,273
Intermediate	Approximate numeric midpoint*	2,522	2,540	2,557
Lower	125	2,802	2,822	2,841

*The intermediate MOOP limit would be based on the related mandatory MOOP cost sharing limit, less approximately 50 percent of the numeric difference between the mandatory and voluntary MOOP cost sharing limits.

We expect to publish the annual inpatient hospital acute and psychiatric limits with a description of how the regulation standard is applied (that is, the methodology used) through HPMS memos issued prior to bid submission each year. We solicit comment on whether additional regulation text is necessary to establish when those memos should be released. We also refer readers to Table 8, which includes the proposed inpatient hospital acute and psychiatric cost sharing limits (for all length of stay scenarios) using the methodology we have proposed in § 422.100(f)(6)(iv). These are only projections of potential inpatient hospital acute and psychiatric cost sharing limits for contract years 2022 through 2024 to illustrate the potential impact of our proposal for incorporating the out-of-pocket costs of Medicare FFS beneficiaries with diagnoses of ESRD into the most recent, complete Medicare FFS data used to set the MA inpatient hospital acute and psychiatric limits. We intend to apply the proposed revised regulations each year to calculate the inpatient hospital acute and psychiatric limits.

CMS requests comments and suggestions on its application and implementation of this proposal for these cost sharing standards. CMS also seeks comments and suggestions on whether additional regulation text or restructuring of § 422.100(f)(6)(iv) is needed to achieve CMS's goal of providing additional transparency on how CMS will: (1) Develop the seven length of stay scenarios for inpatient hospital acute and psychiatric services; (2) transition ESRD costs into inpatient hospital acute and psychiatric limit calculations; and (3) calculate inpatient hospital acute and psychiatric limits after the ESRD cost transition is complete.

3. Basic Benefits for Skilled Nursing Facilities (SNFs), Outpatient, and Professional Services Subject to Cost Sharing Limits (§§ 422.100(j))

We are also proposing to codify and adopt specific cost sharing limits for certain benefits (by individual service and by category) that are based on a comparison to the cost sharing applicable in the Medicare FFS program. For example, the cost sharing limit for days 21–100 in a SNF is calculated by taking one eighth of the projected Part A deductible for the applicable contract year. In addition, the cost sharing limit for days 1 to 20 in a SNF is set at $0 for MA plans that establish a mandatory MOOP limit and MA plans that establish a lower or intermediate MOOP limit are permitted nominal cost sharing limits to align with Medicare FFS and balance incentives for the various types of MOOP limits. In codifying the current policy and in proposing to add new limits, we are relying on both section 1852(a)(1)(B)(iv)(IV) and section 1852(b) of the Act. Section 1852(a)(1)(B)(iv)(IV) of the Act explicitly authorizes the Secretary to identify services that the Secretary determines appropriate (including services that the Secretary determines require a high level of predictability and transparency for beneficiaries) to be subject to a cost sharing limit that is tied to the cost sharing imposed for those services under original Medicare. We have traditionally relied on how higher cost sharing for these benefits discriminates against the enrollees who need these services in establishing limits in the past. Charging higher cost sharing for specific services discriminates against and discourages enrollment by beneficiaries with a health status that requires those services.

Following the discussion is a detailed chart (Table 5) which illustrate the cost sharing limits based on the methodology proposed for contract year 2022, similar to the chart CMS included in the annual Call Letter in past years. Table 5 is based on applying the rules we have proposed in §§ 422.100(f)(6) and (j)(1) and (2) and 422.113(b)(2)(v) and (vi).

a. Range of Cost Sharing Limits for Certain Outpatient and Professional Services

As noted in the 2020 Final Call Letter, CMS has an established policy of affording MA plans greater flexibility in establishing Parts A and B cost sharing when the MA plan adopts a lower, voluntary MOOP limit; less flexibility is available to plans that adopt the higher, mandatory MOOP limit. In contract year 2020, CMS provided this flexibility, on varying levels, for a number of service categories. For example, service categories where we have allowed greater cost sharing flexibility included the first 20 days of a stay at a SNF, emergency care/post stabilization care, home health, and all categories of durable medical equipment (DME).

CMS developed this proposal to provide MA organizations with benefit design flexibilities and to balance beneficiary incentives for each type of MOOP. Accordingly, CMS is proposing to modify the regulation at § 422.100(f)(6) to establish a range of cost sharing limits based upon the MOOP limit established by the MA plan for specific basic benefits (as defined in § 422.100(c)(1)) offered on an in-network basis.

CMS proposes to add § 422.100(f)(6)(iii) to specify that for basic benefits that are professional services furnished in-network, MA plans may have greater flexibility in setting cost sharing based on the MOOP

limit they establish. In our proposal for paragraph (f)(6)(iii), discussed in detail at section VI.B.1. of this proposed rule, we address the type of data that will be used to set cost sharing limits for those professional services and, in proposed paragraphs (f)(6)(iii)(C)(*1*), (*2*), and (*3*) to specify the maximum cost sharing limit based on the MOOP limit established by the MA plan. In addition to those cost sharing limits, we are also proposing to amend § 422.100(j) to impose cost sharing limits for specific benefits and specific categories of benefits that are based on the cost sharing used in original Medicare. Our proposal for § 422.100(j) also takes into account the MOOP type used by an MA plan to grant additional cost sharing flexibility to MA plans. Therefore, under our proposed rule as a whole, multiple standards will apply to the cost sharing for professional services and outpatient benefits. Table 5 in this section summarizes these proposals by illustrating the copayment limits that would be applicable to in-network cost sharing for basic benefits, using projections based on the most recent, complete data that is currently available.

CMS will, in its annual review of plan cost sharing, monitor both copayment amounts and coinsurance percentages. Although MA plans have the flexibility to establish cost sharing amounts as copayments or coinsurance, MA plans should keep in mind, when designing their cost sharing, that enrollees generally find copayment amounts more predictable and less confusing than coinsurance. Copayments are expected to reflect specific benefits identified within the PBP service category or a reasonable group of benefits or services provided. Some PBP service categories may identify specific benefits for which a unique copayment would apply (for example, category 7a includes primary care services), while other categories include a variety of services with different levels of costs which may reasonably have a range of copayments based on groups of similar services (for example, category 15 includes Part B drugs—other which covers a wide range of products and costs). We note that MA plans may establish one cost sharing amount for multiple visits provided during an episode of care (for example, several sessions of cardiac rehabilitation) as long as the overall (or total) cost sharing amount satisfies CMS standards. If the proposals for §§ 422.100(f)(6) and (j) and 422.113(b)(2)(v) and (vi) are finalized, contract year 2022 bids must reflect enrollee cost sharing for in-network services no greater than the amounts calculated using the rules in those regulations. For example, CMS would permit an MA plan that establishes a lower MOOP limit to establish up to 50 percent coinsurance or actuarial equivalent copayment for cardiac rehabilitation (a professional service for which cost sharing is subject to § 422100(f)(6)(iii)), and other services included in Table 5 where we do not propose a specific actuarially equivalent copayment limit. MA organizations have the option to charge either coinsurance or a copayment for most service category benefits.

b. Emergency and Urgently Needed Services (§ 422.113(b)(2)(v) and (vi))

Most of these proposals for limiting cost sharing for basic benefits use methodologies that permit CMS to annually update the dollar amount applicable to copayments while the coinsurance limits would remain at a specified percentage of the total MA plan financial liability. CMS believes a different approach for emergency services is appropriate, as our analyses with OACT find shifts in payment trends may affect emergency services costs more so than urgently needed services and encompass care for a more complex patient. In addition, CMS recognizes that MA plans are able to manage urgently needed services similar to professional services like primary and specialty care in a manner that may not be appropriate or applicable for emergency services. Accordingly, we propose to codify in existing regulation at § 422.113(b)(2)(v) that a maximum cost sharing limit permitted per visit for emergency services corresponds to the MOOP limit established by the MA plan. Our proposal also incorporates elements from the current rule at § 422.113(b)(2)(v), which requires MA organizations to limit cost sharing to enrollees for emergency services that is the lesser of what the enrollee would pay for the services if they were obtained through the MA organization or the amount CMS sets annually.

We are proposing, at § 422.113(b)(2)(v), effective for contract year 2022 and subsequent years, that the MA organization is financially responsible for emergency and urgently needed services with a dollar limit on emergency services including post-stabilization services costs for enrollees that is the lower of—

(A) The cost sharing established by the MA plan if the emergency services were provided through the MA organization; or

(B) A maximum cost sharing limit permitted per visit that corresponds to the MA plan MOOP limit as follows:

(1) $115 for MA plans with a mandatory MOOP limit.

(2) $130 for MA plans with an intermediate MOOP limit.

(3) $150 for MA plans with a lower MOOP limit.

To develop this proposal, CMS looked to the projected median total allowed amount for emergency services (including visit and related procedure costs) using the most recent, complete Medicare FFS data that includes 100 percent of the out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD. We propose to include 100 percent of ESRD costs instead of a gradual transition as the difference in median amounts without ESRD costs and with 100 percent of ESRD costs for contract year 2022 is only $4 ($759 versus $755). The proposal for the cost sharing limits for an MA plan with a mandatory MOOP limit and an MA plan with a lower MOOP limit are tied to the dollar figures that are 15 percent and 20 percent of that median cost, rounded to the nearest whole $5 increment. For example, we reached the mandatory MOOP limit amount by multiplying the projected median total allowed amount for emergency services/post stabilization care with 100 percent of ESRD costs ($755) by 15 percent, which equals $113.25. Then we rounded to the nearest whole $5 increment ($115). The proposed maximum cost sharing limits for MA plans with an intermediate MOOP limit is based on the numeric midpoint of the related cost sharing limits for MA plans with mandatory and lower MOOP limits, rounded to the nearest whole $5 increment. In consultation with the OACT, CMS determined that using the projected median allowed amounts from the most recent, complete Medicare FFS with 100 percent of related ESRD costs (versus projected average Medicare FFS allowed amounts) was more appropriate given the distribution of emergency services and shifts in payment trends. CMS will monitor trends and consider updating cost sharing limits for both urgently needed services and emergency services in future rulemaking based on emerging trends.

In addition, CMS believes it can be difficult for enrollees to differentiate emergency services from post-stabilization services and as such, proposes clarifying updates to the language within paragraph (b)(2)(v) to note that cost sharing limits for emergency services include post-stabilization service costs. We are also proposing to set cost sharing limits for

urgently needed services that are subject to § 422.113(b)(2)(vi). We believe that urgently needed services are most like professional services and therefore, are proposing that the same cost sharing limits for professional services under § 422.100 will apply to urgently needed services, regardless whether those urgently needed services are furnished in-network or out-of-network. We are not proposing any changes to § 422.113 regarding the MA organization's obligations to cover and pay for emergency services, post-stabilization services, and urgently needed services but only to codify specific cost sharing limits for those services.

c. Services No Greater Than Original Medicare

Section 1852(a)(1)(B) of the Act specifies that MA plans may not charge enrollees higher cost sharing than is charged under original Medicare for chemotherapy administration services (which we have implemented as including Part B—chemotherapy/radiation drugs integral to the treatment regimen), skilled nursing care, and renal dialysis services. This rule is currently implemented in §§ 417.454(e) (for cost plans) and 422.100(j) (for MA plans). We are proposing to restructure § 422.100(j) as part of codifying cost sharing limits for other services. Under our proposal, cost sharing standards for cost plans will remain the same. In our current interpretation and application of this requirement for skilled nursing care, we have addressed the first 20 days of a SNP stay differently than days 21 through 100. In Medicare FFS, there is no cost sharing for the first 20 days of a SNP stay. MA plans that establish a voluntary MOOP limit can establish per-day cost sharing for the first 20 days of a SNF stay, but the total cost sharing for the overall SNF benefit (that is, days 1 through 100) must be no higher than the actuarially equivalent cost sharing in original Medicare and the per-day cost sharing for days 21 through 100 must not be greater than the projected original Medicare SNF amount. MA plans that establish the higher, mandatory MOOP limit must establish $0 per-day cost sharing for the first 20 days of a SNF stay and the per-day cost sharing for days 21 through 100 must not be greater than the original Medicare SNF amount. Under our proposal for § 422.100(j)(1)(iii), the current rule for MA plans that use the higher, mandatory MOOP limit will remain the same; we are proposing to permit limited cost sharing for the first 20 days of SNF for MA plans that establish either the lower or intermediate MOOP limit beginning in contract year 2022.

We propose to add the following services to the requirement that cost sharing charged by an MA plan may not exceed cost sharing required under original Medicare: (1) Home health services (as defined in section 1861(m) of the Act) for MA plans that establish a mandatory or intermediate MOOP limit and (2) Durable medical equipment (DME). For home health services, we are also proposing that when the MA plan establishes the lower MOOP limit, the MA plan may have cost sharing up to 20 percent of the total MA plan financial liability. Under our proposal, the DME per-item or service cost sharing must not be greater than original Medicare for MA plans that establish a mandatory MOOP limit. For MA plans that establish a lower or intermediate MOOP limit, total cost sharing for all DME PBP service categories combined must not exceed original Medicare on a per member per month actuarially equivalent basis, but such MA plan may establish cost sharing for specific items of DME that exceed the cost sharing under original Medicare. In order to codify these changes at § 422.100(j), we are proposing to reorganize that paragraph with new text at paragraph (j)(1) to provide that for the basic benefits specified, an MA plan may not establish in-network cost sharing that exceeds the cost sharing required under original Medicare. We are proposing to re-designate existing paragraphs (j)(1) through (3) as (j)(1)(i) through (iii) and to add new paragraphs (j)(1)(iv) (for home health) and (v) (for DME).

d. In-Network Service Category Cost Sharing Requirements

To provide context for our proposal to establish the methodology to set the various cost sharing limits in proposed §§ 422.100(f)(6) and (j) and 422.113(b)(2)(v) and (vi), we provide illustrative cost sharing limits for contract year 2022 in Table 5 based on that methodology and projections of the most recent, complete Medicare FFS data. Table 5 illustrates the coinsurance and copayment standards that would apply only to in-network Parts A and B services (unless otherwise indicated in the table as an application of the rules proposed at §§ 422.100(f)(6)(i) and 422.113(b)(2)(v) and (vi)) for the corresponding type of combined MOOP limit a MA plan chooses to establish. These are only projections of potential cost sharing limits for contract year 2022 to illustrate the potential impact of our proposal. If the proposal for the various amendments to §§ 422.100(f) and (j) and 422.113(b)(2)(vi) regarding cost sharing limits are adopted, we will update these numbers on an annual basis to establish the specific cost sharing limits MA organizations would not be permitted to exceed in establishing their benefit designs. Consistent with our proposal at § 422.113(b)(2)(v), the cost sharing limits for emergency services would remain the same each year unless the regulation is amended. We intend to apply the proposed revised regulations each year to calculate the cost sharing limits unless otherwise stated. We expect to publish the annual inpatient hospital acute and psychiatric limits with a description of how the regulation standard is applied (that is, the methodology used) through HPMS memoranda issued prior to bid submission each year. Under our proposal, all standards and cost sharing are inclusive of applicable service category deductibles, copayments and coinsurance, but do not include plan level deductibles. These cost sharing limits are based on projections of the most recent, complete Medicare FFS data that includes 100 percent of the out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD for basic benefits that are professional services, emergency services/post stabilization care, and urgent care. We propose to include 100 percent of ESRD costs versus a transition of ESRD costs over time as there were no significant difference when including ESRD for any of the physician specialties based on projections of the most, recent complete Medicare FFS from the OACT. For the service categories with only coinsurance limits (that is, limits defined as not applicable (N/A)), and those with $0 or nominal limits (such as SNF), we note that the related ESRD costs are not applicable. For example, our methodology of setting the SNF cost sharing limit for days 21 to 100 only considers the projected Part A deductible from the most recent, complete Medicare FFS data which is not affected by beneficiaries with diagnoses of ESRD enrolling in MA.

In Table 5 we do not include approximate actuarially equivalent copayment limits for: Cardiac rehabilitation, intensive cardiac rehabilitation, pulmonary rehabilitation, supervised exercise therapy (SET) for symptomatic peripheral artery disease (PAD), partial hospitalization, home health, therapeutic radiological services, DME, dialysis, Part B Drugs Chemotherapy/Radiation Drugs, and Part B Drugs—Other. In general, we found these categories are subject to a higher variation in cost or unique provider contracting arrangements

which makes using Medicare FFS average or median cost data less applicable for developing a standardized actuarially equivalent copayment value. As such, in order to monitor and enforce compliance with these cost sharing requirements that are based on the contracted rates the MA plan uses for in-network services, MA organizations may be required to provide information to CMS demonstrating how contracted rates comply with the regulation standards we are proposing here at § 422.100(f)(6). We solicit comment whether an explicit regulatory provision should be added to require MA organizations to demonstrate compliance with these standards upon request by CMS; such demonstration would include providing CMS with information substantiating the contracted rates for basic benefits that are professional services for which CMS has not established an approximate actuarially equivalent copayment limits, and illustrating how the MA organization determined its cost sharing amounts.

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TABLE 5: ILLUSTRATIVE CONTRACT YEAR 2022 IN-NETWORK SERVICE CATEGORY COST SHARING LIMITS

Service Category	PBP Section B data entry field	Lower MOOP	Intermediate MOOP	Mandatory MOOP
Inpatient Hospital – Acute - 60 days	1a	N/A	$5,514	$4,902
Inpatient Hospital – Acute - 10 days	1a	$2,802	$2,522	$2,242
Inpatient Hospital – Acute - 6 days	1a	$2,536	$2,282	$2,029
Inpatient Hospital Acute – 3 days	1a	$2,339	$2,105	$1,872
Inpatient Hospital Psychiatric - 60 days[6]	1b	$3,408	$3,067	$2,726
Inpatient Hospital Psychiatric - 15 days[6]	1b	$2,339	$2,105	$1,871
Inpatient Hospital Psychiatric – 8 days[6]	1b	$2,173	$1,955	$1,738
Skilled Nursing Facility – First 20 Days [1,2]	2	$20	$10	$0
Skilled Nursing Facility – Days 21 through 100 [1,2,7]	2	$184/d	$184/d	$184/d
Cardiac Rehabilitation[5]	3	50%	40%	30%
Intensive Cardiac Rehabilitation[5]	3	50%	40%	30%
Pulmonary Rehabilitation[5]	3	50%	40%	30%
Supervised exercise therapy (SET) for Symptomatic peripheral artery disease (PAD)[5]	3	50%	40%	30%
Emergency Care/Post Stabilization Care[3]	4a	$150	$130	$115
Urgently Needed Services[3]	4b	50% / $55	40% / $45	30% / $35
Partial Hospitalization[5]	5	50%	40%	30%
Home Health	6a	20%[5]	$0	$0
Primary Care Physician	7a	50% / $55	40% / $45	30% / $35
Chiropractic Care	7b	50% / $25	40% / $20	30% / $15
Occupational Therapy	7c	50% / $60	40% / $45	30% / $35
Physician Specialist	7d	50% / $80	40% / $65	30% / $50
Mental Health Specialty Services	7e	50% / $65	40% / $55	30% / $40
Psychiatric Services	7h	50% / $65	40% / $50	30% / $40
Physical Therapy and Speech-language Pathology	7i	50% / $85	40% / $65	30% / $50
Therapeutic Radiological Services[5]	8b	20%	20%	20%
DME-Equipment	11a	N/A	N/A	20%[5]
DME-Prosthetics	11b	N/A	N/A	20%[5]
DME-Medical Supplies	11b	N/A	N/A	20%[5]

Service Category	PBP Section B data entry field	Lower MOOP	Intermediate MOOP	Mandatory MOOP
DME-Diabetes Monitoring Supplies	11c	N/A	N/A	20%[5]
DME-Diabetic Shoes or Inserts	11c	N/A	N/A	20%[5]
Dialysis Services[1,5]	12	20%	20%	20%
Part B Drugs Chemotherapy/Radiation Drugs[1,4, 5]	15	20%	20%	20%
Part B Drugs-Other[5]	15	50%	40%	30%

[1] MA plans and 1876 Cost Plans may not charge enrollees higher cost sharing than is charged under original Medicare for Part B chemotherapy/radiation drugs integral to the treatment regimen, skilled nursing care, and renal dialysis services (§ 417.454(e) and proposed § 422.100(j)(1)(i), (ii), and (iii)).

[2] MA plans that establish a lower and intermediate MOOP limit may have cost sharing for the first 20 days of a SNF stay (proposed § 422.100(j)(1)(iii)). The per-day cost sharing for days 21 through 100 must not be greater than the original Medicare SNF amount, proposed at § 422.100(j)(1)(iii)(A). Total cost sharing for the overall SNF benefit must be no higher than the actuarially equivalent cost sharing in original Medicare, pursuant to section1852(a)(1)(B), and proposed § 422.100(j)(1)(iii)(B).

[3] The dollar amount for Emergency Care/Post Stabilization Care and Urgently Needed Services included in the table represents the maximum cost sharing permitted per visit (copayment or coinsurance) under proposed § 422.113(b)(2)(v) and (vi).

[5] MA plans may set cost sharing limits that are actuarially equivalent to the coinsurance limits based on their contracted rates under proposed § 422.100(f)(6)(iii)(A).

[6] Inpatient hospital psychiatric standards will be updated for contract year 2022 to incorporate differences in Part A deductible and cost impacts for beneficiaries with diagnoses of ESRD.

[7] This SNF limit is based on the 1/8th of the projected contract year 2021 Part A deductible, which will be updated for 2022.

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MA organizations with benefit designs using a coinsurance or copayment amount for which we are not proposing to publish a specific threshold for cost sharing (for example, coinsurance for inpatient or copayment for durable medical equipment) must maintain documentation that clearly demonstrates how the coinsurance or copayment amount satisfies the regulatory requirements for each applicable plan. This is consistent with existing MA program monitoring and oversight for MA organizations to be able to demonstrate compliance with applicable program requirements. Cost sharing and other plan design elements remain subject as well to § 422.100(f)(2), which prohibits MA plans from designing benefits to discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services. This documentation may be used to address potential beneficiary appeals, complaints, and/or general oversight activities performed by CMS. In addition, MA plans are required to attest when they submit their bid that their benefits will be offered in accordance with all applicable Medicare program authorizing statutes and regulations.

4. Per Member per Month Actuarial Equivalent (AE) Cost Sharing Limits for Basic Benefits (§ 422.100(j)(2))

Under the statute and current regulations, total MA cost sharing for Parts A and B services must not exceed cost sharing for those services in Medicare FFS on an actuarially equivalent basis and must not be discriminatory. In order to ensure that cost sharing is consistent with both §§ 422.254(b)(4) and 422.100(f)(2), and current § 422.100(f)(6), CMS has historically evaluated cost sharing limits on a per member per month actuarially equivalent basis for the following service categories: Inpatient hospital, SNF, DME, and Part B drugs.

In proposed § 422.100(j)(2), we propose a rule requiring that total cost sharing for all basic benefits covered by an MA plan, excluding out-of-network benefits covered by a regional MA plan, must not exceed cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis. This provision implements section 1852(a)(1)(B) of the Act and the carve out of out-of-network benefits covered by a regional MA plan is to be consistent with section 1852(a)(1)(B)(ii) of the Act. CMS is also proposing to codify our existing policy regarding the specific benefit categories that MA plans must not exceed the cost sharing for those benefit categories in original Medicare on a per member per month actuarially equivalent basis in § 422.100(j)(2)(i). Consistent with existing policy, the services subject to this requirement under our proposal are: (A) Inpatient hospital acute and psychiatric services, defined as services provided during a covered stay in an inpatient facility during the period for which cost sharing would apply under original Medicare; (B) DME; (C) Drugs and biologics covered under Part B of original Medicare (including both chemotherapy/radiation drugs and other

drugs covered under Part B); and (D) Skilled nursing care, defined as services provided during a covered stay in a SNF during the period for which cost sharing would apply under original Medicare.

This proposal would ensure that MA plans with greater cost sharing flexibility in these categories are not designing benefits in a way that discriminates against enrollees with health status factors and conditions that require these services. Further, limiting cost sharing this way will ensure that enrollees with certain conditions or who are high utilizers of these basic benefits are not discouraged from enrolling in MA plans. We are therefore relying on our authority under section 1852(a)(1)(B)(iv) and 1852(a)(2) of the Act to codify these rules requiring MA cost sharing to be limited based on cost sharing in original Medicare. In addition, we believe that setting copayment limits through quantitative formulas (such as those used for our inpatient hospital acute and psychiatric standards) may be less appropriate for some categories, like DME and Part B drugs. Cost sharing for these services may be better evaluated for discrimination on an aggregate service category basis. These categories include items or services that significantly vary in costs and/or may be subject to provider contracting arrangements that makes it difficult and arbitrary for CMS to establish a specific copayment amount for the category as a whole as opposed to specific items and benefits.

We are also proposing, at § 422.100(j)(2)(ii) that CMS may extend flexibility for MA plans when evaluating actuarial equivalent cost sharing limits for those service categories to the extent that the per member per month cost sharing limit is actuarially justifiable based on generally accepted actuarial principles and supporting documentation included in the bid, provided that the cost sharing for specific services otherwise satisfies published cost sharing standards. We believe that this exception will apply in limited situations, such as when the MA plan uses capitated arrangements with provider groups, operate their own facilities, or other unique arrangements. This flexibility codifies and is consistent with current policy and practice.

This proposal aims to clarify how CMS uses the most relevant and appropriate information to determine whether specific cost sharing is discriminatory and to set standards and thresholds above which CMS believes cost sharing is discriminatory. Similar to current practice, CMS intends to use HPMS memoranda to communicate prior to bid submission its application of the regulation for future years, as appropriate. We solicit comment on the previously discussed proposals.

C. Plan Crosswalks for Medicare Advantage (MA) Plans and Cost Plans (§§ 417.496 and 422.530)

We are proposing to codify the current process and conditions under which MA organizations and 1876 cost plans can transfer their enrollees into the same plan or plan type from year to year when no other election has been made (this process is a ''plan crosswalk''), as well as when plans can transfer their enrollees to other plans of a different type offered by the same MA organization or cost plan (this is a ''crosswalk exception''). Our proposal defines plan crosswalks, codifies rules that protect a beneficiary's right to choose a plan, and specifies the circumstances under which MA organizations and cost plans may transfer beneficiaries into another plan of the same type offered by the MA organization or, in the case of cost plans, transfer enrollees from that cost plan benefit package to another plan benefit package (PBP) under the same contract. We generally use the terms ''plan'' and ''PBP'' interchangeably to refer to a specific plan offered under a contract. Specifically, the term PBP is used to describe the individual benefits packages that may be offered under a singular plan. Section 1851(c)(3)(B) of the Act provides for evergreen elections which are when an individual who has made an election is considered to have continued to make the same election until the individual makes a change to the election, or the MA plan is discontinued or no longer serves the area in which the individual resides. In many cases, our crosswalk policy is a mechanism for operationalizing these evergreen elections.

Section 1851 of the Act provides that Medicare beneficiaries who are entitled to Part A and enrolled in Part B may elect to receive benefits through enrollment in an MA plan of their choice and authorizes CMS to adopt the process, form and manner for making and changing enrollment elections. We are proposing to codify existing policy regarding crosswalks and crosswalk exceptions using this authority and our authority under sections 1856(b)(1) and 1857(e)(1) of the Act to adopt standards and contract terms for MA organizations. In furtherance of the beneficiary's right to choose and implementing evergreen elections, CMS is proposing to codify existing policy in new regulations at §§ 417.496 and 422.530 to define plan crosswalks, implement rules that protect a beneficiary's right to choose a plan, and describe allowable circumstances under which MA organizations may transfer beneficiaries from one of its MA plans into another of its MA plans or a cost contract may transfer beneficiaries from one of its plans into another of its cost plans. With respect to cost plans, we are proposing to codify existing enrollment policy related to the transfer of enrollees from an entity's cost plan to another cost plan, under the authority of section 1876(i)(3)(D) of the Act, which requires that cost contracts shall contain such other terms and conditions, not inconsistent with the statute, as the Secretary may find necessary and appropriate. Our proposal does not include rules for deeming enrollment from a cost plan to an MA plan under sections 1876(h)(5)(C) and 1851(c)(4) of the Act. The statute does not permit deeming of enrollees from cost plans to MA plans beyond contract year 2018.

We are also proposing, at § 422.530(d), the procedures that an MA organization must follow when submitting a crosswalk or a crosswalk exception request. An MA organization must submit all allowable crosswalks in writing through the bid submission process in HPMS by the bid submission deadline announced by CMS. Through the bid submission process, the MA organization may indicate if a crosswalk exception request is needed at that time, but the MA organization must request a crosswalk exception later through the crosswalk exception functionality in HPMS by the deadline announced by CMS. CMS verifies the exception request and notifies the requesting MA organization of the approval or denial of the request after the crosswalk exception deadline has expired. These exceptions must be submitted by the MA organization to ensure that plan benefit package (PBP) enrollment is allocated appropriately. We solicit comment on what, if any, additional procedures we should adopt for managing crosswalk exceptions.

CMS has developed extensive guidance addressing the transfer of enrollees from one PBP offered by an organization to another PBP offered by that organization under the same contract.[71] The guidance, applicable to MA organizations and cost plans, was developed in light of the ability of MA organizations and cost plans to revise their benefit offerings and PBPs from year to year. The transfer of enrollees

[71] Chapter 16b of the Medicare Managed Care Manual and Process for Requesting an HPMS Crosswalk Exception for Contract Year (CY) 2020 (released annually).

from one PBP to another under these circumstances serves to facilitate evergreen elections. MA organizations frequently make business decisions resulting in changes of their MA plans offered for enrollment in the following contract year. Each year, through the bid process for plan design and an application process for service area changes, MA organizations submit changes in coverage and cost sharing design for their MA plans. In addition, MA organizations have the ability to terminate existing plans and apply to offer new plans. While cost plan organizations may not offer new cost plans, they also may make changes in their benefit and cost sharing design and seek service area changes through an annual process. CMS has issued annual sub-regulatory guidance related to changes of this type for MA and cost plans to address how MA organizations and cost plans may transition enrollees from a plan that is terminating or changing its service area to another plan offered by the same organization. These transitions are useful to preserve beneficiary enrollment and are subject to a number of beneficiary protections. We are proposing to codify existing crosswalk policy to clearly identify the basic rules for plan crosswalks, including the parameters for allowable crosswalks, and formalize CMS's crosswalk exception review process. Crosswalk exceptions are specific circumstances where a crosswalk is not automatically authorized under our policies but CMS permits MA organizations and cost plans to transfer beneficiaries into another plan of the same type offered by the MA organization or cost plan after a review, provided that certain requirements are met. The crosswalk exceptions process would allow CMS to review and validate the existence of an exception, and then manually effectuate the transaction in our system. Crosswalk exceptions are not part of the standard, annual PBP renewal process. These new regulations would be codified at §§ 417.496 and 422.530 to govern, respectively, cost plans and MA organizations.

We are proposing, at §§ 417.496(a)(1) and 422.530(a)(1), to define a plan crosswalk as the movement of enrollees from one PBP to another PBP under the same contract between the MA or cost organization and CMS. MA and cost organizations complete these crosswalk transactions annually as part of the renewal process. Unlike MA plans, however, cost plans do not include different plan types such as PPOs, PFFS, and special needs plans, therefore in § 417.496(a)(2), we are not specifying, as we are for the MA section, that crosswalks from one plan type to another are prohibited.

In § 422.530(a)(5), we propose to define the types of MA plans that we consider different for purposes of crosswalk policy. We propose that health maintenance organizations, provider-sponsored organizations, and regional and local preferred provider organizations coordinated care plans are different plan types, even though they are all coordinated care plans. Additionally, we note here that the segmented plans are not a ''type'' of plan in MA and that crosswalks are permitted between segmented and non-segmented plans. We do not include in the cost plan crosswalk regulation that contract transactions related to plan types and policies such as segmentation and continuation, which are specific to MA contract transactions. The majority of crosswalks involve moving enrollees from one contract year plan to the corresponding plan for the following contract year. Therefore, enrollees are not required to make an enrollment election to remain enrolled in their chosen plan. In § 417.496(a)(2)(i), we are proposing to codify the general rule, that crosswalks are prohibited between different cost contracts and in § 417.496(a)(2)(ii), we are proposing to codify that crosswalks are prohibited between different cost plan IDs under a cost contract unless the crosswalk qualifies for an exception to this requirement. In § 417.496(c)(1)(i) and (ii) we propose to codify the exception that cost contracts terminating PBPs with optional supplemental benefits may transfer enrollees to another PBP with or without optional benefits under the same cost contract as long as enrollees who have Part A and B benefits only are not transferred to a PBP that includes Part D. In § 417.496(c)(1)(iii)(A), (B), and (C), we propose to codify that an enrollee in a terminating PBP that includes Part D may only be moved to a PBP that does not include Part D if the enrollee is notified in writing that she/he is losing Part D coverage, the options for obtaining Part D, and the implications of not getting Part D through some other means. In § 422.530(a)(2), we are proposing to codify the general rule that crosswalks are prohibited between different MA contracts or different plan types (for example, HMO to PPO). This means that crosswalks are only permitted between plans of the same type under the same contract. However, we are also proposing, in § 422.530(c), the limited circumstances in which CMS will allow a crosswalk transaction that does not comply with this general prohibition on crosswalks to different contracts. We include in § 422.530(a)(2) a reference to these ''exceptions'' permitted under paragraph (c). The exceptions we are proposing in § 422.530(c) apply to MA plans only as they pertain to MA policies so we are not proposing similar regulation text in § 417.496.

As most plan crosswalks are related to contract renewals and non-renewals, we are also proposing a general rule at § 422.530(a)(3) to require that MA plans must comply with renewal and nonrenewal rules in §§ 422.505 and 422.506 in order to be eligible to complete plan crosswalks. In § 417.496(a)(3), we are proposing that cost plans must comply with the renewal and non-renewals per §§ 417.490 and 417.492, in order to be eligible to complete plan crosswalks. In § 422.530(a)(4), we are proposing that enrollees must be eligible for enrollment under §§ 422.50 through 422.54 in order to be moved from PBP to another PBP.

In §§ 422.530(b) and 417.496(b), we propose to codify the existing crosswalk policy by specifying the circumstances under which a crosswalk is permitted so that an MA organization or cost plan may move enrollees into, respectively, another MA plan or cost plan. For MA plans, in proposed paragraph (b)(1), we address permissible crosswalks for all plan types and in proposed paragraph (b)(2), we address crosswalks that are permissible only for MA special needs plans (SNPs). We remind readers that the MA plan types are identified in § 422.4; therefore, we specified in § 422.530(a)(5) that the different types of coordinated care plans are considered different ''plan types'' for purposes of crosswalking policy. For cost plans, in proposed paragraph (b), we address permissible crosswalks for cost plans.

1. Cost Plans and All MA Plan Types

a. Renewal Plan

An MA or cost organization may continue to offer, that is, renew, a current PBP that retains all of the same service area for the following year; the renewing plan must retain the same PBP ID number as in the previous contract year. We are proposing to codify this as a permissible crosswalk in paragraph (b)(1)(i) for MA plans and § 417.496(b)(1) for Cost plans. Current enrollees are not required to make an enrollment election to remain enrolled in the renewal PBP, and the MA or cost organization will not submit enrollment transactions to CMS for current enrollees but will transition all enrollees

from the current PBP to the new PBP with the same PBP ID number for the following year. New enrollees must complete enrollment requests, and the MA or cost organization will submit enrollment transactions to CMS for those new enrollees. Under §§ 422.111 and 417.427 current MA and cost enrollees of a renewed PBP, respectively, must receive an Annual Notice of Change (ANOC) notifying them of any changes to the renewing plan.

b. Consolidated Renewal Plan

MA and cost organizations may combine two or more PBPs offered under the same contract in the current contract year into a single renewal plan, as a plan consolidation. When the consolidation includes two or more complete PBPs being combined and no PBP being split among more than one PBP in the next contract year, the MA or cost organization is permitted to transition all enrollees in the combined plans under one PBP under that contract, with the same benefits in the following contract year; the resulting PBP must have the plan ID of one of the consolidated plans. We are proposing to codify this as a permissible crosswalk in §§ 417.496(b)(2) and 422.530(b)(1)(ii). Current enrollees of a plan or plans being consolidated into a single renewal plan will not be required to take any enrollment action, and the MA or cost organization does not submit enrollment transactions to CMS for those current enrollees. The renewal PBP ID is used to transition current enrollees of the plans being consolidated into the designated renewal plan. In operationalizing this crosswalk, the MA or Cost organization may need to submit updated data to CMS for the enrollees affected by the consolidation. New enrollees in the consolidated renewal plan must complete enrollment forms and the MA or cost organization must submit the enrollment transactions to CMS for those new enrollees. Under §§ 422.111 and 417.427 MA and Cost plans, respectively, are required to provide an ANOC to all current enrollees in the consolidated renewal plan.

c. Renewal Plan With a Service Area Expansion (SAE)

An MA or cost organization may continue to offer the same cost plan or local MA plan but expand the service area to include one or more additional counties for the following contract year. To expand the service area of its plan(s), an MA or cost organization must submit a service area expansion (SAE) application to CMS for review and approval; CMS treats service area expansions as applications subject to the rules in part 422, subpart K, and § 417.402. An MA or cost organization renewing a plan with a SAE must retain the renewed PBP's ID number in order for all current enrollees to remain enrolled in that plan the following contract year. Current enrollees of a PBP that is renewed with a SAE are not required to take any enrollment action, and the MA or cost organization does not submit enrollment transactions to CMS for those current enrollees but will transition all enrollees from the current PBP to the new PBP with the same PBP ID number for the following year. We are proposing to codify this as a permissible crosswalk in § 422.530(b)(1)(iii) for MA plans and § 417.496(b)(3) for cost plans. New enrollees must complete enrollment forms and the MA or cost organization must submit the enrollment transactions to CMS for those new enrollees. Under §§ 422.111 and 417.427 MA and cost plans, respectively, are required to provide an ANOC to all current enrollees of a renewed PBP with a SAE.

d. Renewal Plan With a Service Area Reduction

An MA organization offering a local MA plan may reduce the service area of a current contract year PBP; similarly, a cost organization may reduce the service area of a cost plan. This service area reduction (SAR) means that enrollees who were in the part of the service area being reduced will generally not be eligible to remain in the plan because of the residence requirement in §§ 417.422(b), 422.50(a)(3), and 422.54. We propose to address crosswalks that may occur in connection with a service area reduction in §§ 422.530(b)(1)(iv) and 417.496(b)(4). We are proposing that when there is a service area reduction for a plan, the MA organization or cost plan may only crosswalk the enrollees who reside in the remaining service area to the plan in the following contract year that links to a current contract year plan but only retains a portion of the prior service area. The following contract year plan must retain the same plan ID as the current contract year plan. The crosswalk is limited to the enrollees in the remaining service area. MA organizations may have different options available to them in terms of notices and the ability to offer a continuation of enrollment under § 422.74(b)(3)(ii) depending on the other MA plans in the area at the time of the service area reduction. We are proposing regulation text to address the different scenarios.

In § 422.530(b)(1)(iv)(C), we propose that enrollees that are no longer in the service area of the MA or cost plan will be disenrolled at the end of the contract year and will need to elect another plan (or default to original Medicare). The MA or cost organization must submit disenrollment transactions to CMS for these enrollees. In addition, the MA or cost plan organization must send a Medigap guaranteed issue rights to the affected enrollees and a non-renewal notice to enrollees in the reduced portion of the service area that includes notification of special election period (SEP). We are also proposing to codify, at § 422.530(b)(1)(iv)(D) specific rules about what information may be provided by the MA organization about its other MA plan options in the area that will no longer be part of the service area of the continued plan. Per the marketing and communication regulations, we are proposing at §§ 422.2263(a) and 423.2263(a) and discussed elsewhere in this proposed rule, marketing information about other MA plan options offered by the MA organization for the prospective plan year can begin October 1 of each year for the following contract year.

2. Special Needs Plans (SNPs)

Under our current crosswalk policies, MA Special Needs Plans (SNPs) follow the general rules, which we propose to codify in § 422.530(b)(1), and are permitted additional flexibility for crosswalks in specific situations. We propose to codify regulation text to identify the additional crosswalks permitted for SNPs in § 422.530(b)(2). These additional scenarios vary based on the type of SNP. We reiterate that MA organizations may not crosswalk enrollees from one SNP type to a different SNP type, as that would constitute crosswalking into a different type of plan, which is prohibited by proposed § 422.530(a)(2).

(a) Chronic Condition SNPs (C–SNPs): We are proposing to codify four permissible crosswalks specific to C–SNPs at § 422.530(b)(2)(ii)(A) through (D). C–SNPs serve and are limited to enrolling special needs individuals who have a severe or disabling chronic condition(s) and would benefit from enrollment in a specialized MA plan. The MA organization offering the C–SNP may target one or more specific severe or disabling chronic conditions. When a C–SNP targets more than one severe or disabling chronic condition, we refer to that as a ''grouping'' and we have addressed groupings in guidance in Chapter 16b of the Medicare Managed Care Manual. These permissible crosswalks reflect the limitations on

eligibility for C–SNPs, as different C–SNPs serve different populations depending on the chronic condition(s) targeted for enrollment restriction.

A. Renewing C–SNP with one chronic condition that transitions eligible enrollees into another C–SNP with a grouping that contains that same chronic condition.

B. Non-renewing C–SNP with one chronic condition that transitions eligible enrollees into another C–SNP with a grouping that contains that same chronic condition.

C. Renewing C–SNP with a grouping that is transitioning eligible enrollees into another C–SNP with one of the chronic conditions from that grouping.

D. Non-renewing C–SNP in a grouping that is transitioning eligible enrollees into a different grouping C–SNP if the new grouping contains at least one condition that the prior plan contained.

(b) Institutional-SNPs:

We are proposing to codify five permissible crosswalks specific to I–SNPs at § 422.530(b)(2)(iii)(A) through (E). I–SNPs are limited to enrolling individuals who are institutionalized or institutionalized-equivalent, as those terms are defined in § 422.2. I–SNPs may limit their enrollment to either institutionalized or institutionalized-equivalent individuals or may enroll both categories of individuals. These permissible crosswalks reflect the enrollment limitations on I–SNPs.

A. Renewing Institutional SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

B. Renewing Institutional Equivalent SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

C. Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional SNP.

D. Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional Equivalent SNP.

E. Non-renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to another Institutional/Institutional Equivalent SNP.

(c) Dual Eligible-SNPs (D–SNPs):

We are not proposing to codify any permissible crosswalks specific to D–SNPs.

e. Exceptions

In some instances, crosswalk actions must be manually reviewed and entered by CMS staff. We call these *crosswalk exceptions.* We propose to codify at § 422.530(c) when CMS will approve a request for a crosswalk exception and permit crosswalks in situations that are not specified in § 422.530(b). These exceptions address certain unusual circumstances involving specific types of plans or contract activities. Under our proposal, only an exception specified in § 422.530(c) would be approved and recognized as an additional circumstance when a crosswalk is permitted. We propose the following exceptions to the limits on the crosswalk process:

1. When a non-network or partial network based private fee-for-service (PFFS) plan is transitioning to either a partial network or a full network PFFS plan, we are proposing to permit a crosswalk when CMS determines it is in the interest of beneficiaries. CMS will consider whether the risks to enrollees are such that they would be better served by remaining in the plan, whether there are other suitable managed care plans available, and whether the enrollees are particularly medically vulnerable, such as institutionalized enrollees. We anticipate that granting these exceptions would be extremely rare since in the great majority of instances enrollees have choices of multiple MA plans or Original Medicare and are able to exercise their choice. We are specifically proposing to restrict crosswalks between these network and non-network PFFS plans because the way enrollees will access health care services is significantly different in each of these plans. Section 1852(d)(5) of the Act establishes that in areas that are determined to be ''network areas'' PFFS plans can only operate by having a network of providers that meets CMS current network adequacy standards. The network based PFFS plan functions very much like a MA PPO plan in that there is a network of contracted providers through which enrollees can obtain Medicare covered services. In addition, an enrollee in a network based PFFS plan has the option of also going out-of-network for plan covered services though their cost sharing may be higher. However, in areas of the country that have determined to be non-network areas with respect to PFFS plans, the PFFS plan can operate without a network and enrollees must seek care from any willing provider under the non-network PFFS plans terms and conditions of payment. Because these two types of PFFS plans function very differently for enrollees obtaining covered health care services, we do not believe crosswalks should be generally permitted between these two types of PFFS plans.

2. When MA plans offered by two different MA organizations that share the same parent organization are consolidated such that the MA plans under separate contracts consolidated under one surviving contract, the enrollees from the consolidating plans may be moved to an MA plan under the surviving plan. As a result of the consolidation of contracts, enrollees from at least one of the PBPs are transitioned to another contract; therefore, CMS limits approval of these crosswalks to an exception because of the movement across different contracts. As part of reviewing a request for this crosswalk exception, CMS reviews the contract consolidation to ensure compliance with the change of ownership regulations (§§ 422.550 through 422.553).

3. Renewing D–SNP in a multi-state service area that is reducing its service area to accommodate a state contract in part of the service area. When a renewing D–SNP in a multi-state service area reduces its service area to accommodate state contracting efforts in the service area, we are proposing to permit a crosswalk exception at § 422.530(c)(3). Under this proposed crosswalk exception, enrollees who are no longer in the service area would be moved into one or more new or renewing D–SNPs in their service area, when CMS determines it is necessary to accommodate changes to D–SNP state contracts.

4. Renewing D–SNP that transitions eligible enrollees into another D–SNP. We propose a crosswalk exception at § 422.530(c)(4) for circumstances where an MA organization renews a D–SNP for the upcoming contract year, but has another available new or renewing D–SNP for the upcoming contract year, and the two D–SNPs are offered to different populations. An MA organization may change—or as part of state contracting, may be required to change—a D–SNP's eligibility criteria for the upcoming contract year. As a result, some current enrollees may no longer be eligible for their current D–SNP. However, the MA organization may have a new or renewing D–SNP in the same service area with eligibility requirements that can accommodate the enrollees who are no longer eligible for their current D–SNP. In such cases, CMS may determine it is in the best interests to current enrollees who are no longer eligible for their D–SNP to allow such a crosswalk exception.

5. Renewing C–SNP with a grouping that is transitioning eligible enrollees into another C–SNP with one of the chronic conditions from that grouping. This crosswalk exception differs from

the allowable crosswalk in § 422.530(b)(2)(i)(B) because it is a renewing C–SNP and not a non-renewing C–SNP. A crosswalk exception is required in order for CMS to identify which enrollees are moving from the renewing plan C–SNP to the other C–SNP. In a non-renewing C–SNP, all enrollees would be crosswalked to another plan or disenrolled.

CMS crosswalk policies are designed to protect the rights of enrollees to make a choice about the plan from which they wish to receive Medicare benefits while facilitating how section 1851(c)(3)(B) of the Act requires evergreen elections. This proposal would codify policies and standards CMS has implemented that allow MA and Cost organizations the flexibility to make business decisions about the benefit and cost sharing design of a plan while preserving the rights of beneficiaries to make informed choices about their health care coverage. We invite comments about codifying our existing plan crosswalk policies.

D. Medicare Advantage (MA) Change of Ownership Limited to the Medicare Book of Business (§ 422.550)

Section 1857 of the Act requires each MA organization to have a contract with CMS in order to offer an MA plan. Section 1857(e)(1) of the Act authorizes the adoption of additional contract terms that are consistent with the statute and that the Secretary finds are necessary and appropriate. Consistent with this authority, at the beginning of the Part C program we implemented contracting regulations in § 422.550 which provide for the novation of an MA contract in the event of a change of ownership involving an MA organization. (63 FR 35106) Under the regulations, codified at §§ 422.550 through 422.553, the execution of a novation agreement is required when an MA organization is acquired or when it no longer is able or desires to continue to participate in the MA program and wants to transfer its ownership to a different entity. When an MA organization is no longer able or willing to participate in the MA program, a change of ownership can provide both the holder of the contract and CMS with an opportunity to transfer the ownership of the contract to a different entity with little or no disruption to enrolled beneficiaries. In this instance, CMS would agree to a novation of the existing MA contract because it promotes the efficient and effective administration of the MA program.

We propose to revise § 422.550 by adding a new paragraph at § 422.550(f) to restrict the situations in which CMS will agree to an MA contract novation to those transfers involving the selling of the organization's entire line of MA business, which would include all MA contracts held by the legal entity that is identified as the MA organization. It has been long-standing policy in the MA program that CMS will only recognize the sale or transfer of a legal entity's entire MA line, or book of business, consisting of all MA contracts held by the MA organization because we believe that allowing the sale of just one contract (when the MA organization has more than one MA contract) or pieces of a single contract can have a negative impact on beneficiary election rights. The proposed change would codify existing policy and also create more consistency in regulations between the Part D program and the MA program as stated in § 423.551(g).

This policy has not been applied in cases where contracts are transferred among subsidiaries of the same parent organization. We do not wish to interfere with an MA organization's (or parent organization's) ability to decide its corporate structure or contractual arrangements with its subsidiaries. Therefore, we are also proposing, at § 422.550(f)(1) an exception to the proposed limit for changes of ownership to only when the entire MA book of business is being transferred; that exception would be when the sale or transfer is of a full contract between wholly owned subsidiaries of the same parent organization.

We are proposing to codify explicitly in § 422.550(f)(2) that CMS will not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries, groups of beneficiaries enrolled in a plan benefit package, or one MA contract if the organization holds more than one MA contract. We reiterate that we believe that allowing the sale of just one contract (when the MA organization has more than one MA contract) or pieces of a single contract can have a negative impact on beneficiary election rights.

E. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)

Section 1852(d)(1)(A) of the Act establishes that an organization offering an MA plan may select the providers from whom the benefits under the plan are provided so long as the organization makes such benefits available and accessible with reasonable promptness to each individual electing the plan within the plan service area. This is generally implemented at § 422.112(a), which provides that a coordinated care plan must maintain a network of appropriate providers that is sufficient to provide adequate access to covered services to meet the needs of the population served. In the April 15, 2010, Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program Final Rule (75 FR 19691), CMS added criteria at § 422.112(a)(10) for determining whether an MA plan network is adequate and meets the statutory standard by codifying that MA plans must have networks that are consistent with the prevailing community pattern of health care delivery in the service area. The regulation provides that CMS will consider factors that make up the community patterns of health care, which CMS will use as a benchmark in evaluating MA plan networks, and lists certain examples of those factors in § 422.112(a)(10)(i) through (v). CMS explained in the October 22, 2009, Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule (74 FR 54644) that it would develop an automated system for reviewing network adequacy based on the elements that define community patterns of health care delivery and that we would define through subregulatory guidance how CMS would operationalize these factors.

Since that time, CMS has routinely provided subregulatory guidance to MA organizations that defines how CMS measures and assesses network adequacy.[72] We built the Network Management Module (NMM) in HPMS to facilitate automated reviews of plan networks and to annually transmit information to MA plans about provider/facility specialty types that are subject to specific network adequacy standards, maximum time and distance standards, minimum number requirements, and other critical information needed for the network adequacy reviews. The NMM also gave existing MA organizations and new applicants to the MA program the opportunity to routinely test their networks against our standards. Currently, CMS requires that organizations contract with a sufficient number of specified providers/facilities to ensure that 90 percent of the beneficiaries have access to at least one provider/facility of each specialty type within the published maximum time and distance standards. CMS updates and refines the data and information that feed into network adequacy

[72] *See* ''Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance''—*https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/index.*

measures and CMS performs analyses as needed. It is important that CMS ensure that MA organizations maintain an adequate network of contracted providers that are capable of providing medically necessary covered services to beneficiaries, both to ensure compliance with section 1851(d) of the Act and to protect beneficiaries. The network adequacy rules protect beneficiaries by ensuring that most, it not all, of the beneficiaries enrolled in a plan have access to providers within a reasonable time and distance from where the beneficiaries reside.

We propose to codify existing network adequacy standards to provide MA organizations with a greater understanding of how CMS measures and assesses network adequacy. We propose to codify in § 422.116 the list of provider and facility specialty types subject to network adequacy reviews, county type designations and ratios, maximum time and distance standards, minimum number requirements, and exceptions. The proposed regulation would also address CMS's annual publishing of the Provider Supply file and Health Service Delivery (HSD) reference file to release updated numbers and maximums for these standards in subsequent years. We also propose to modify our current network adequacy policy to further account for access needs in all counties, including rural counties, and to take into account the impact of telehealth providers in contracted networks. Section 1876(c)(4) of the Act imposes similar requirements for cost plans offered under section 1876 of the Act to make Medicare-covered services available and accessible to each enrollee with reasonable promptness when medically necessary. Under this authority, we are also proposing to amend § 417.416(e) to require 1876 cost organizations to also comply with the network adequacy standards described in proposed § 422.116.

We propose in § 422.116(a) that each network-based MA plan demonstrate that it has an adequate contracted provider network that is sufficient to provide access to medically necessary covered services consistent with standards in section 1851(d) of the Act, the regulations at §§ 422.112(a) and 422.114(a), and the rules in new § 422.116. Under our proposal, an MA plan would demonstrate its compliance as part of our triennial evaluation using the adequacy standards identified in § 422.116. In addition, we are proposing that, when required by CMS, an MA organization must attest that it has an adequate network for access and availability of a specific provider or facility type that CMS does not independently evaluate in a given year. We anticipate that we would require such attestation in the MA organization's application or contract for a given year but we might require the attestation when performing other network adequacy reviews, such as when there is a significant change in the MA plan's provider network.

We are proposing to cross-reference § 422.114(a)(3)(ii) to identify the network-based plan types that would be subject to these network adequacy requirements. Network-based MA plans include all coordinated care plans in § 422.4(a)(1), network-based MA private-fee-for-service (PFFS) plans in § 422.4(a)(3), and 1876 cost organizations. Generally, network-based MA medical savings account (MSA) plans are considered coordinated care plans in accordance with § 422.4(a)(1)(iii)(D), which includes ''other network plans'' as a type of coordinated care plan. However, since MSA plans do not require contracted networks, we propose to exclude MSA plans from the requirements in § 422.116. By cross-referencing § 422.114(a)(3)(ii), our proposal would carve out an MA regional plan that meets access requirements substantially through deemed contracting, so local and regional PFFS plans operating in CMS defined network areas must meet CMS network adequacy requirements at § 422.116 under our proposal.

We are also proposing, at paragraph (a)(2), to codify the general rule underlying § 422.116 that an MA plan must meet maximum time and distance standards and contract with a specified minimum number of each provider and facility specialty type, with each contract provider type within maximum time and distance of at least one beneficiary in order to count toward the minimum number. Under our proposal, the minimum number criteria and the time and distance criteria vary by the county type. We propose to establish the specific provider and facility types; county types; specific time and distance standards by county designation; and specific minimum provider number requirements in paragraphs (b), (c), (d) and (e), respectively, of § 422.116. Regardless of whether CMS evaluates a plan's network against the access and adequacy standards in a given year, a plan's network must meet these standards and will be held to full compliance with the standards. At paragraphs (a)(3) through (4), we are proposing to codify additional general rules about the network adequacy requirements in this section. At paragraph (a)(3), we propose general rules for which provider types are not counted in evaluating network adequacy; we discuss this specific proposal in connection with proposed paragraph (b). In paragraph (a)(4), we are proposing to codify certain administrative practices we have instituted over the past several years. Specifically, we propose to codify that CMS will annually update and make available Health Service Delivery (HSD) reference files in advance of our review of plan networks. These HSD files contain the minimum provider and facility number requirements, minimum provider ratios, and the minimum time and distance standards. We are also proposing to codify that CMS will annually update and make available a Provider Supply file that identifies available providers and facilities with office locations and specialty types. The Provider Supply file is updated annually based on information from the Integrated Data Repository (IDR), which has comprehensive claims data, as well as information from public sources. CMS may also update the Provider Supply file based on findings from validation of provider information.

We propose to codify at § 422.116(b) the list of provider and facility specialty types that have been subject to CMS network adequacy standards in the past, as not all specialty types are included in network adequacy reviews. The proposed regulation text identifies the 27 provider specialty types and 14 facility specialty types that are currently used in the evaluation of network adequacy in each service area. CMS has identified these provider and facility specialty types as critical to providing services based on review of Medicare FFS) utilization patterns, utilization of provider/facility specialty types in Medicare FFS and managed care programs, and the clinical needs of Medicare beneficiaries. We propose to codify at § 422.116(a)(3) existing policy identifying provider and facility types that are not counted in evaluating network adequacy: Specialized, long-term care, and pediatric/children's hospitals and providers and facilities contracted with the organization only for its commercial, Medicaid, or other non-MA plans. In paragraph (a)(3), we also propose that hospital-based dialysis may count in network adequacy criteria for the facility type of Outpatient Dialysis. We clarify that primary care providers, the first provider specialty in our proposed list in paragraph (b)(1), are measured as a single specialty by combining provider specialty codes (001–006) in the HSD reference file. Otherwise, we believe that the list of

provider and facility types in proposed paragraphs (b)(1) and (2) are fairly self-explanatory.

Section 2005 of the SUPPORT Act establishes a new Medicare Part B benefit for OUD treatment services furnished by Opioid Treatment Programs (OTPs) on or after January 1, 2020. OTPs provide medication-assisted treatment for people diagnosed with an Opioid Use Disorder and must be certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and accredited by an independent, SAMHSA-approved accrediting body. We have not proposed to include OTPs as a facility type in § 422.116(b)(2) due to the newness of the benefit and we may consider adding OTPs to the facility type list in future proposals. However, we remind MA organizations that they are required to pay for medically necessary care from certified OTPs, regardless of the location of the OTP.

The lists of provider and facility specialty types that we have used in the network adequacy evaluations have seen very few changes over the past 5 years, so we believe that codifying the lists currently in use is appropriate. However, we expect that, from time to time, it may not be necessary to evaluate the number and accessibility of each of the 27 specialty and 14 facility types in a particular year. Therefore, we propose at § 422.116(b)(3) that CMS may remove a specialty or facility type from the network adequacy evaluation for a particular year by not including the type in the annual publication of the HSD reference file. For example, in the past CMS removed oral surgery from the HSD reference file, and replaced home health and durable medical equipment with an attestation in its application about the plan's network ensuring access to providers of these types. Under our proposed authority at § 422.116(a)(1) to require an MA plan to submit an attestation when required by CMS, we would require an MA organization to complete an attestation that it has an adequate network that provides the required access to and availability of provider specialty or facility types even where we do not evaluate access ourselves. Network adequacy criteria are measured for each individual specialty type and do not roll up into an aggregate score. Therefore, the removal of a specialty type from the network review will not affect the outcome of an MA plan's network review and use of an attestation in lieu of evaluation will permit us some necessary flexibility. In light of the lack of change to the list we have used over the past several years, we are not proposing any means for CMS to add new provider specialty or facility types to the network adequacy evaluation without additional rulemaking.

We propose at § 422.116(c) to codify our current policy regarding county designations. Network adequacy is assessed at the county level, and counties are classified into five county type designations: Large Metro, Metro, Micro, Rural, or CEAC (Counties with Extreme Access Considerations). These metrics provide the means by which the various network adequacy criteria are differentiated to represent large geographic variations across the United States and its territories. They are based on the population size and the population density of each county. We propose to codify at § 422.116(c) the five county type designations using population size and density parameters. We propose to codify the population size and density parameters in Table 6.

TABLE 6: POPULATION SIZE AND DENSITY PARAMETERS

COUNTY DESIGNATION	POPULATION	DENSITY
Large Metro	≥ 1,000,000	≥ 1,000/mi^2
	500,000 – 999,999	≥ 1,500/mi^2
	Any	≥ 5,000/mi^2
Metro	≥ 1,000,000	10 – 999.9/mi^2
	500,000 – 999,999	10 – 1,499.9/mi^2
	200,000 – 499,999	10 – 4,999.9/mi^2
	50,000 – 199,999	100 – 4,999.9/mi^2
	10,000 – 49,999	1,000 – 4,999.9/mi^2
Micro	50,000 – 199,999	10 – 99.9/mi^2
	10,000 – 49,999	50 – 999.9/mi^2
Rural	10,000 – 49,999	10 - 49.9/mi^2
	< 10,000	50 - 999.9/mi^2
CEAC	Any	< 10/mi^2

A county must meet both the population and density parameters for inclusion in a given county type designation. These parameters are consistent with those we have used in conducting network adequacy reviews in prior years. We have based the parameters on approaches used by the United States Census Bureau in its classification of ''urbanized areas'' and ''urban clusters,'' and by the Office of Management and Budget (OMB) in its classification of ''metropolitan'' and ''micropolitan.'' To calculate population density at the county level, we divided the latest county-level population [73] estimate by the land area [74] for that county. This county designation methodology was designed specifically for MA network adequacy and may not be appropriate for other purposes.

We propose in § 422.116(a)(2) that network adequacy is measured using both maximum time and distance standards and minimum number requirements that vary by county type. In § 422.116(d), we propose that CMS determines maximum time and distance

[73] United States Census Bureau. American Factfinder. Annual Estimates of the Resident Population: April 1, 2010 to July 1, 2018: 2018 Population Estimates. Retrieved from: *https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2017_PEPANNRES&src=pt.*

[74] United States Census Bureau. American Factfinder. Population, Housing Units, Area, and Density: 2010—United States—County by State; and for Puerto Rico: 2010 Census Summary File 1. Retrieved from: *https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=DEC_10_SF1_GCTPH1.US05PR&prodType=table.*

standards by county type and specialty type and publishes these standards annually in the HSD Reference file. Maximum time and distance standards are set by county designation, referred to as the ''base'' time and distance standards, or by a process referred to as ''customization.'' We propose to codify the base time and distance standards by county designation that are in current practice with recent network reviews. See Table 7.

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TABLE 7: BASE TIME AND DISTANCE STANDARDS

	Large Metro		Metro		Micro		Rural		CEAC	
Provider/Facility Type	**Max Time**	**Max Distance**	**Max Time**	**Max Distance**	**Max Time**	**Max Distance**	**Max Time**	**Max Distance**	**Max Time**	**Max Distance**
Primary Care	10	5	15	10	30	20	40	30	70	60
Allergy and Immunology	30	15	45	30	80	60	90	75	125	110
Cardiology	20	10	30	20	50	35	75	60	95	85
Chiropractor	30	15	45	30	80	60	90	75	125	110
Dermatology	20	10	45	30	60	45	75	60	110	100
Endocrinology	30	15	60	40	100	75	110	90	145	130
ENT/Otolaryngology	30	15	45	30	80	60	90	75	125	110
Gastroenterology	20	10	45	30	60	45	75	60	110	100
General Surgery	20	10	30	20	50	35	75	60	95	85
Gynecology, OB/GYN	30	15	45	30	80	60	90	75	125	110
Infectious Diseases	30	15	60	40	100	75	110	90	145	130
Nephrology	30	15	45	30	80	60	90	75	125	110
Neurology	20	10	45	30	60	45	75	60	110	100
Neurosurgery	30	15	60	40	100	75	110	90	145	130
Oncology - Medical, Surgical	20	10	45	30	60	45	75	60	110	100
Oncology - Radiation/Radiation Oncology	30	15	60	40	100	75	110	90	145	130
Ophthalmology	20	10	30	20	50	35	75	60	95	85
Orthopedic Surgery	20	10	30	20	50	35	75	60	95	85
Physiatry, Rehabilitative Medicine	30	15	45	30	80	60	90	75	125	110
Plastic Surgery	30	15	60	40	100	75	110	90	145	130

	Large Metro		Metro		Micro		Rural		CEAC	
Provider/Facility Type	**Max Time**	**Max Distance**	**Max Time**	**Max Distance**	**Max Time**	**Max Distance**	**Max Time**	**Max Distance**	**Max Time**	**Max Distance**
Podiatry	20	10	45	30	60	45	75	60	110	100
Psychiatry	20	10	45	30	60	45	75	60	110	100
Pulmonology	20	10	45	30	60	45	75	60	110	100
Rheumatology	30	15	60	40	100	75	110	90	145	130
Urology	20	10	45	30	60	45	75	60	110	100
Vascular Surgery	30	15	60	40	100	75	110	90	145	130
Cardiothoracic Surgery	30	15	60	40	100	75	110	90	145	130
Acute Inpatient Hospitals	20	10	45	30	80	60	75	60	110	100
Cardiac Surgery Program	30	15	60	40	160	120	145	120	155	140
Cardiac Catheterization Services	30	15	60	40	160	120	145	120	155	140
Critical Care Services – Intensive Care Units (ICU)	20	10	45	30	160	120	145	120	155	140
Outpatient Dialysis	20	10	45	30	65	50	55	50	100	90
Surgical Services (Outpatient or ASC)	20	10	45	30	80	60	75	60	110	100
Skilled Nursing Facilities	20	10	45	30	80	60	75	60	95	85
Diagnostic Radiology	20	10	45	30	80	60	75	60	110	100
Mammography	20	10	45	30	80	60	75	60	110	100
Physical Therapy	20	10	45	30	80	60	75	60	110	100
Occupational Therapy	20	10	45	30	80	60	75	60	110	100
Speech Therapy	20	10	45	30	80	60	75	60	110	100

	Large Metro		Metro		Micro		Rural		CEAC	
Provider/Facility Type	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance
Inpatient Psychiatric Facility Services	30	15	70	45	100	75	90	75	155	140
Outpatient Infusion/Chemotherapy	20	10	45	30	80	60	75	60	110	100

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CMS established the base time and distance standards proposed here by mapping the various specialty types' practice locations from the National Provider and Plan Enumeration System (NPPES) National Provider Identifier (NPI) file compared with Medicare beneficiary locations from CMS enrollment data. We then tested different options for combinations of beneficiary coverage percentages and maximum travel distances to determine what was feasible and practical for the majority of counties given the trade-off between beneficiary coverage and travel distance. The travel time standards were calculated according to the average driving speeds in each of the ZIP code types (urban, suburban, rural) that beneficiaries would traverse between their homes and the provider locations.

While the base time and distance criteria are not updated regularly, criteria for some specialty types within some county types have been updated over the past few years. These updates generally have been done to reflect a significant change in the supply of providers in an area, and when the new county designation methodology was implemented (that is, moving from classifying counties based on metropolitan statistical areas to the current county designations). In our current practice and under our proposal, the designation of each particular county is not static but is based on the application of specific population size and density standards. If a county designation changes as a particular type under the rules proposed in § 422.116(c), the time and distance standards for that county will also change, consistent with the standards we are proposing in § 422.116(d). In the annual HSD Reference File that CMS publishes, and would continue to publish under our proposal at paragraph (a)(4)(i), the county designation and applicable time and distance standards for each county will be identified for the applicable year.

CMS currently requires that organizations contract with a sufficient number of providers/facilities to ensure that 90 percent of the beneficiaries have access to at least one provider/facility of each specialty type within the published maximum time and distance standards. The location of a contracted provider specialty or facility is not required to be within the county or state boundaries to be considered within the time and distance standards.

In recent years, we have added flexibility to expand the time (in minutes) and distance (in miles) standards beyond the base standards, in cases where, due to a shortage of supply of providers or facilities, it is not possible to meet the base time and distance standards. We propose to codify this process at § 422.116(d)(3) and refer to it as ''customization.'' To customize distance standards, we use software to map provider location data from the Provider Supply file against the population distribution data in CMS's MA Medicare Sample Census.[75] For each specialty and county where there are insufficient providers within the base distance standard, we use mapping results to identify the distance at which 90% of the population would have access to at least one provider or facility in the applicable specialty type. The resulting distance is then rounded up to the next multiple of five (51.2 miles would be rounded up to 55 miles), and a multiplier specific to the county designation is applied to determine the analogous maximum time criterion. We request comment on our customization methodology and whether we should adjust factors in the distance calculation to achieve outcomes that are more equitable. For example, CMS could adjust the percentage of the population from 90%, or we could require more than one provider or facility to be within distance of the designated percentage of the population.

Customization of base criteria may be triggered based on information received through exception requests from plans, or from other sources, such as certificates of need (CON) from state departments of health. However, we propose that CMS may only use customization to increase time and distance standards from the base standards, and may not reduce time and distance standards below the base standards. CMS may consider relevant information when creating network adequacy standards in accordance with § 422.112(a)(10)(i)–(v), and therefore, we solicit comment from the industry on other sources of information that CMS should consider and how it would work within the structure of our network adequacy standards.

Historically, CMS has required that at least 90 percent of the beneficiaries residing in a particular county have access to at least one provider/facility of each specialty type within the published maximum time and distance standards for that county. In this rule, and in an effort to encourage more MA offerings in rural areas, we propose to reduce this percentage to 85 percent in Micro, Rural, and CEAC counties. In these generally ''rural'' counties, there is evidence of a lower supply of physicians, particularly specialists, compared to urban areas.[76] In order to account for this shortage, two state Medicaid programs that utilize network adequacy criteria have adjusted percentages in rural counties to require that standards be met for less than 100 percent of enrollees. New Jersey allows an 85 percent coverage requirement for primary care in ''non-urban counties''

[75] CMS built the MA Medicare Sample Census, which derives from information maintained by CMS on the residence of Medicare beneficiaries. CMS built the Sample Census to be an adequate representative sample of Medicare beneficiaries in each applicable county. This file is only available to CMS and is only utilized for the purposes of measuring network adequacy.

[76] Department of Health and Human Services, National Advisory Committee on Rural Health and Human Services (2018) ''Rural Health Insurance Market Challenges: Policy Brief and Recommendations.'' Retrieved April 3, 2019, from: *https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/rural/publications/2018-Rural-Health-Insurance-Market-Challenges.pdf.*

but 90 percent in urban counties.[77] Tennessee's Medicaid Managed Care program takes a slightly different approach, requiring that 60 percent of enrollees have access within 60 miles and 100 percent within 90 miles.[78] Additionally, the Part D program has a 90 percent retail pharmacy network coverage requirement in urban and suburban areas that drops to 70 percent for rural areas.[79] Further, our data indicates that existing failures in MA plans' meeting the time and distance standards frequently occur at the range between 80–89 percent of beneficiaries. As a result, we propose to adopt a similar change in our MA network adequacy approach to account for access challenges in Micro, Rural, and CEAC counties; we are proposing at § 422.116(d)(4)(i) to require that at least 85 percent of the beneficiaries have access to at least one provider/facility of each specialty type within the published time and distance standards in Micro, Rural, and CEAC counties. We estimate that approximately 14 percent of contracts (96 contracts) operating in these county designations will benefit from the reduced percentage and will no longer need to submit an exception request. We propose to codify the existing policy of using a 90 percent threshold for Large Metro and Metro counties in § 422.116(d)(4)(ii). We note that this specific proposal does not include a change from current policy requirements for a minimum number of provider specialties and facilities and that we are proposing, at paragraph (e), that MA plans will still be required to maintain contracts with a minimum number of providers in each county.

We also propose to give an MA plan a 10-percentage point credit towards the percentage of beneficiaries residing within the applicable time and distance standards for certain provider specialty types when the plan contracts with telehealth providers for those specified specialty types. For example, in a rural county where an MA plan must have 85 percent of beneficiaries residing within applicable time and distance standards, the MA plan will receive an additional 10 percentage points towards the 85 percent requirement should they contract with applicable telehealth providers under § 422.135. This is not currently part of the network adequacy evaluation, but we believe it is appropriate in light of the expanding coverage in the MA program of additional telehealth benefits. In the April 2019 final rule, we adopted § 422.135 to implement the option for MA plans to offer additional telehealth benefits as part of their coverage of basic benefits under section 1852(m) of the Act, as amended by section 50323 of the BBA of 2018. In that rulemaking, we solicited feedback from the industry concerning the impact, if any, that telehealth should have on network adequacy policies. We received thirty-five responses from stakeholders in managed care, provider, advocacy, and government sectors. While health plans clearly favored taking into account telehealth access while evaluating network adequacy, providers had more concerns that telehealth services could be used to replace in-person healthcare delivery. One commenter stated that it is imperative that beneficiaries continue to have the choice to access services in-person not only as a matter of preference, but to ensure those that do not have access to the required technologies aren't left without care. Section 1852(m)(4) of the Act and the regulation at § 422.135(c)(1) require that an enrollee in an MA plan offering additional telehealth benefits must retain the choice of receiving health care services in person rather than through electronic exchange (that is, as telehealth). With that in mind, and emphasizing the importance of maintaining an in-person network, we are not proposing any changes to how we currently calculate minimum provider requirements. Under our proposal, MA plans must still contract with a minimum number of providers for each specialty type. We believe this is imperative for MA plans to be able to provide in-person care when needed or when preferred by the beneficiary. However, contracting with telehealth providers as a supplement to an existing in-person contracted network will give enrollees more choices in how they receive health care. We believe it is important and appropriate to account for contracted telehealth providers in evaluating network adequacy consistent with reflecting how MA plans supplement, but do not replace, their in-person networks with telehealth providers. We are proposing, at § 422.116(d)(5) to provide a 10-percentage point credit towards the percentage of beneficiaries residing within time and distance standards for specific provider specialty types by county when the MA plan includes one or more telehealth providers that provide additional telehealth benefits, as defined in § 422.135, in its contracted network. Since additional telehealth benefits described at § 422.135 only apply to MA plans, cost plans will not be eligible for this 10-percentage point credit.

We believe a 10-percentage point credit is an appropriate amount that proportionately supplements a plan's percentage score because telehealth providers add value to a contracted provider network, but should not have the same level of significance or value as an in-person provider. Additionally, information from prior network adequacy reviews show that many failures in meeting time and distance standards occur in this 80–89% range. Therefore, our proposal for a 10-percentage point credit is significant enough to have an impact on MA plans and encourage the use of telehealth, and proportionate to the role that telehealth providers have in a contracted network. Further, we propose to apply this telehealth credit only to specific provider specialty types: Dermatology, psychiatry, neurology, otolaryngology and cardiology. We believe this limited approach will allow CMS to appropriately monitor the effectiveness of the proposal, while also allowing us to determine whether there may be access or quality of care impacts. As we discussed in the April 2019 final rule, additional telehealth benefits are monitored by CMS through account management activities, complaint tracking and reporting, and auditing activities. These oversight operations will alert CMS to any issues with access to care and CMS may require MA organizations to address these matters if they arise.

CMS considered feedback from industry stakeholders, publicly available studies, and analyses of Medicare claims data for telehealth services in determining applicable provider specialty types. We considered not only the potential that telehealth has within a specialty type, but also the observed access challenges for provider specialty types over the years of our network adequacy reviews. CMS has observed that most MA plans do not have challenges meeting time and distance standards for primary care as compared to non-primary care provider specialty types. We also believe that it is critical to quality health care that Medicare beneficiaries have a primary care provider that they can visit in

[77] State of New Jersey Dept of Human Services. ''Contract Between State of New Jersey Department of Human Services Division of Medical Assistance and Health Services and _____, Contractor'' Sec. 4.8.8 ''Provider Network Requirements'' Retrieved April 5, 2019, from: *https://www.state.nj.us/humanservices/dmahs/info/resources/care/hmo-contract.pdf.*

[78] State of Tennessee, Department of Finance and Administration, Division of Health Care Finance and Administration, Division of TennCare (2019) ''Statewide Contract with Amendment 9—January 1, 2019'' Attachment IV. Retrieved April 3, 2019, from: *https://www.tn.gov/content/dam/tn/tenncare/documents/MCOStatewideContract.pdf.*

[79] Section 423.120(a)(1).

person and within a suitable time and distance. Therefore, despite the potential and prevalence of telehealth for furnishing primary care services, we do not believe that it is necessary to take telehealth access into account when measuring and setting minimum standards for access to primary care providers. CMS solicits comments on the appropriateness of the provider specialty types eligible for the telehealth credit and whether CMS should expand or limit this list to a different set of provider specialties.

CMS has received comments from providers and physician groups about the limitations of current network adequacy policies on dialysis treatment when performed in a hospital, at home, or in an outpatient facility. Some research suggests that home-based dialysis may offer advantages over in-center hemodialysis, including patient convenience, reduction in costs associated with dialysis, and potentially improved patient quality of life and blood pressure control with greater survival and fewer hospitalizations.[80] We recognize that there is more than one way to access medically necessary dialysis care and we want plans to exercise all of their options to best meet a beneficiary's health care needs. Therefore, we are considering several options about how to improve our proposal as it relates to measuring and setting minimum standards for access to dialysis services. We solicit comment on: (1) Whether CMS should remove outpatient dialysis from the list of facility types for which MA plans need to meet time and distance standards; (2) allowing plans to attest to providing medically necessary dialysis services in its contract application (as is current practice for DME, home health, and transplant services) instead of requiring each MA plan to meet time and distance standards for providers of these services; (3) allowing exceptions to time and distance standards if a plan is instead covering home dialysis for all enrollees who need these services; and (4) customizing time and distance standards for all dialysis facilities.

CMS has also received comments concerning patterns of provider consolidation and its impact on higher costs for patients. CMS has heard from stakeholders that providers in concentrated areas may leverage network adequacy requirements in order to negotiate prices well above Medicare FFS rates. We solicit comment on existing problems and behavior in non-rural, consolidated provider markets and recommendations that CMS could take to encourage more competition in these markets.

President Trump's Executive Order 13890 on Protecting and Improving Medicare for Our Nation's Seniors (October 3, 2019) calls for adjustments to network adequacy requirements to account for the competitiveness of state health care markets, including taking into account whether states maintain Certificate of Need (''CON'') laws or other anticompetitive restrictions. Many states began adopting CON laws in the 1960s and 1970s in part to promote resource savings and to prevent investments that could raise hospital costs.[81] A number of studies have found no evidence that CON programs have led to resource savings, and in some instances, may raise health care costs. In one study published in 2013, researchers studied whether states that dropped CON programs experienced changes in costs or reimbursements from coronary artery bypass graft surgery or percutaneous coronary interventions.[82] In this study, the cost savings from removing the CON requirements slightly exceeded the total fixed costs of new facilities that entered after deregulation. Another study published in 2016 concluded that there is no evidence that CON requirements limit health care price inflation and little evidence that they reduce health care spending.[83] It further concluded that CON laws are associated with higher per unit costs and higher total healthcare spending. Most relevant here, other studies suggest that the removal of these laws that serve as a barrier to entry into the market lead to greater access to providers and a redistribution of health care services to higher quality providers, improving the overall quality of health outcomes.[84]

As this research points out, CON laws restrict the supply and competition for healthcare services and increases costs. Therefore, CON laws adversely affect access in states and counties where they are in effect, including for MA organizations that operate in those areas. CMS pays MA organizations a capitated amount in each county for the provision of Medicare benefits based on the expected costs to provide benefits. When MA organizations must pay more for benefits, as the research demonstrates happens when there are fewer providers or facilities with which to contract, that reduces the access to benefits offered by MA organizations. In order to take into account the adverse effects that CON laws have on access, we propose in § 422.116(d)(6) to provide that MA organizations may receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected provider and facility types in states that have CON laws, or other state imposed anti-competitive restrictions, that limit the number of providers or facilities in a county or state. As discussed below, under our proposal, where appropriate, CMS may instead address network adequacy by customizing base time and distance standards in States with CON laws. We believe this proposal is justified based on the studies cited previously that have shown that CON laws adversely affect competition and free market entry in states and that our network adequacy policy thus should provide for us to consider this factor when evaluating the adequacy of an MA organization's contracted network.

We propose to make this credit equal to and in addition to, if applicable, the telehealth credit (10 percentage points) discussed earlier in this proposal. We chose a 10-percentage point credit for CON laws for reasons similar to those that we selected the 10-percentage point credit for the telehealth specialties; that is information from prior network adequacy reviews show that many failures in meeting time and distance standards occur in the 80–89% range. Under our proposal, CMS may elect to grant this credit instead of customizing time and distance standards depending on a number of factors like the speed of implementing customized standards, operational and timing constraints, and the amount of work required to calculate customized time and distance standards. We solicit comment on additional criteria or factors we should consider when deciding whether to apply the 10-percentage point credit or customize time and distance standards in the impacted states or counties. Additionally, we solicit comment about what other actions CMS could take in markets with state CON laws.

We are also considering whether there are circumstances where a more limited

[80] Comparative Effectiveness of Home-Based Kidney Dialysis Versus In-Center or Other Outpatient Kidney Dialysis Locations—A Systematic Review [internet]: *https://www.ncbi.nlm.nih.gov/books/NBK344417/.*

[81] Daniel Sherman, ''The Effect of State Certificate-of-Need Laws on Hospital Costs: An Economic Policy Analysis,'' *Federal Trade Commision,* January 1988.

[82] Vivian Ho, Meei-Hsiang Ku-Goto, ''State Deregulation and Medicare Costs for Acute Cardiac Care,'' *Med Care Res Rev.,* April 2013.

[83] Matthew D. Mitchell, ''Do Certificate-of-Need Laws Limit Spending?'' *Mercatus Working Paper,* Mercatus Center at George Mason University, Arlington, VA, September 2016.

[84] David M. Cutler, Robert S. Huckman, and Jonathan T. Kolstad, ''Input Constraints and the Efficiency of Entry: Lessons from Cardiac Surgery,'' *American Economic Journal: Economic Policy,* February 2010.

application of network adequacy flexibility might be more appropriate. We solicit comment as to how and under what circumstances we should refrain from applying the 10 percentage point credit, should mitigate the size of this credit, or other actions we might undertake to apply this flexibility in a more limited manner.

We are proposing to codify the current policy that MA plans must contract with a specified minimum number of each provider and facility specialty type in § 422.116(e). The MA plan must have a minimum number of in-person providers and facilities in each county for each specialty type specified in paragraph (b). We propose at § 422.116(e)(1) the general rules that the provider or facility must be within the maximum time and distance of at least one beneficiary in order to count towards the minimum number requirement and cannot be a telehealth-only provider. We are also proposing to codify the methodology for establishing the minimum number requirements for specific contracted provider and facility specialty types per county. Under our proposal, CMS will use this methodology each year to determine and publish the updated minimum provider standards on an annual basis. Certain standards for the minimum number of providers are updated annually to account for changes in the Medicare population, MA market penetration, and county designations. Under our current policy and our proposal, the provider/facility must be within the maximum time and distance of at least one beneficiary in order to count towards the minimum number requirements.

We proposed to codify our existing practice in § 422.116(e)(2)(iii) that all facilities, except for acute inpatient hospitals facilities, have a minimum number requirement of one. We are proposing to limit the methodology for establishing and changing the required minimum number standard to acute inpatient hospitals and other non-facility provider specialties. We propose the methodology at § 422.116(e)(3): CMS determines the minimum number requirement for all provider specialty types and Acute Inpatient Hospitals by multiplying the ''minimum ratio'' by the ''number of beneficiaries required to cover,'' dividing the resulting product by 1,000, and rounding up to the next whole number. The steps and components of the methodology are proposed in paragraphs (e)(3)(i) and (ii).

The Minimum Ratio is the number of providers required per 1,000 beneficiaries, and for Acute Inpatient Hospitals, the number of beds per 1,000 beneficiaries. CMS established minimum ratios in 2011 using a number of data sources, including, Medicare fee-for-service claims data, American Medical Association (AMA) and American Osteopathic Association (AOA) physician workforce data, US Census population data, National Ambulatory Medical Care Survey data, AMA data on physician productivity, and published literature. We propose to codify the Minimum Ratios at § 422.116(e)(3)(i) as shown in Table 8.

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TABLE 8: MINIMUM RATIOS

MINIMUM RATIO	LARGE METRO	METRO	MICRO	RURAL	CEAC
Primary Care	1.67	1.67	1.42	1.42	1.42
Allergy and Immunology	0.05	0.05	0.04	0.04	0.04
Cardiology	0.27	0.27	0.23	0.23	0.23
Chiropractor	0.10	0.10	0.09	0.09	0.09
Dermatology	0.16	0.16	0.14	0.14	0.14
Endocrinology	0.04	0.04	0.03	0.03	0.03
ENT/Otolaryngology	0.06	0.06	0.05	0.05	0.05
Gastroenterology	0.12	0.12	0.10	0.10	0.10
General Surgery	0.28	0.28	0.24	0.24	0.24
Gynecology, OB/GYN	0.04	0.04	0.03	0.03	0.03
Infectious Diseases	0.03	0.03	0.03	0.03	0.03
Nephrology	0.09	0.09	0.08	0.08	0.08
Neurology	0.12	0.12	0.10	0.10	0.10
Neurosurgery	0.01	0.01	0.01	0.01	0.01
Oncology - Medical, Surgical	0.19	0.19	0.16	0.16	0.16
Oncology - Radiation/Radiation Oncology	0.06	0.06	0.05	0.05	0.05
Ophthalmology	0.24	0.24	0.20	0.20	0.20
Orthopedic Surgery	0.20	0.20	0.17	0.17	0.17
Physiatry, Rehabilitative Medicine	0.04	0.04	0.03	0.03	0.03
Plastic Surgery	0.01	0.01	0.01	0.01	0.01

MINIMUM RATIO	LARGE METRO	METRO	MICRO	RURAL	CEAC
Podiatry	0.19	0.19	0.16	0.16	0.16
Psychiatry	0.14	0.14	0.12	0.12	0.12
Pulmonology	0.13	0.13	0.11	0.11	0.11
Rheumatology	0.07	0.07	0.06	0.06	0.06
Urology	0.12	0.12	0.10	0.10	0.10
Vascular Surgery	0.02	0.02	0.02	0.02	0.02
Cardiothoracic Surgery	0.01	0.01	0.01	0.01	0.01
Acute Inpatient Hospitals	12.2	12.2	12.2	12.2	12.2

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The Number of Beneficiaries Required to Cover is also calculated by CMS based on an established methodology. The Number of Beneficiaries Required to Cover is the minimum population that an MA plan's network should be able to serve and represents the potential number of beneficiaries an organization may serve within a county. We propose at § 422.116(e)(3)(ii)(A) that the Number of Beneficiaries Required to Cover is calculated by multiplying the ''95th Percentile Base Population Ratio'' times the total number of Medicare beneficiaries residing in a county. CMS uses its MA State/County Penetration data to calculate the total beneficiaries residing in a county. For counties with lower populations, and particularly for specialties with lower minimum ratios, the minimum number is usually one.

The 95th Percentile Base Population Ratio is calculated annually for each county type. Several years ago, CMS allowed MA organizations to provide their expected enrollment and then define their networks based on that number, but we later developed a more objective means to measure network adequacy for all MA plans consistently. The 95th Percentile Base Population Ratio is a fair and consistent enrollment estimate that can be applied to new and current plans. While it varies over time as MA market penetration and plan enrollment changes across markets, the 95th Percentile Base Population Ratio currently ranges between 0.073 and 0.145 depending on county type, indicating that MA plans are expected to have networks at least sufficient to cover between 7.3 percent (Large Metro) and 14.5 percent (CEAC) of the Medicare beneficiaries in the county. This ratio represents the proportion of Medicare beneficiaries enrolled in the 95th percentile MA plan (that is, 95% of plans have enrollment lower than this level).

To calculate the 95th Percentile Base Population Ratio, we use the List of PFFS Network Counties [85] to exclude PFFS plans in non-networked counties [86] from the calculation at the county type level. We use the MA State/County Penetration data [87] to determine the number of eligible Medicare beneficiaries in each county, and our Monthly MA Enrollment data [88] to determine enrollment at the contract ID and county level, including only enrollment in RPPO, LPPO, HMO, HMO/POS, healthcare prepayment plans under section 1833 of the Act, and network PFFS plan types. We calculate penetration at the contract ID and county level by dividing the number of enrollees for a given contract ID and county by the number of eligible beneficiaries in that county. Finally, we group counties by county designation to determine the 95th percentile of penetration among MA plans for each county type. We propose to codify the methodology for calculating the 95th Percentile Base Population Ratio at § 422.116(e)(3)(ii)(B).

Finally, we are also proposing to codify in paragraph (f) a process by which an MA plan may request and receive an exception from the network adequacy standards in § 422.116. CMS conducts network adequacy reviews through an automated process, but also allows for exceptions to that process when failures are detected in the submitted network. We propose to codify the exceptions process, the basis upon which an MA plan may request an exception, and the factors that CMS may consider when evaluating an MA organization's request for an exception to our network standards. An MA organization may request an exception when certain providers or facilities are not available for the MA organization to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type, and the MA organization has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care. For

[85] CMS. PFFS Plan Network Requirements. Retrieved from: *https://www.cms.gov/Medicare/Health-Plans/PrivateFeeforServicePlans/Network Requirements.html.*

[86] Non-networked counties in this context means there are not at least two networked plans operating in that county.

[87] CMS. MA State/County Penetration. Retrieved from: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/MA-State-County-Penetration.html.*

[88] CMS. Monthly MA Enrollment by State/County/Contract. Retrieved from: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-MA-Enrollment-by-State-County-Contract.html.*

example, certain providers/facilities may not be available for contracting when the provider has moved or retired, or when the provider/facility does not contract with any organizations or exclusively with another organization. The MA plan should contract with telehealth providers, mobile providers, or providers outside the time and distance standards, but accessible to most enrollees (or consistent with the local pattern of care) to qualify for an exception by CMS. In evaluating exception requests, CMS will consider: (i) Whether the current access to providers and facilities is different from the HSD reference and Provider Supply files for the year; (ii) whether there are other factors present, in accordance with § 422.112(a)(10)(v), that demonstrate that network access is consistent with or better than the original Medicare pattern of care; and (iii) whether approval of the exception is in the best interests of beneficiaries.

Currently, CMS collects information for purposes of testing an MA organization's network adequacy in the PRA-approved collection titled, ''Triennial Network Adequacy Review for Medicare Advantage Organizations and 1876 Cost Plans, CMS–10636, OMB 0938—New.'' CMS relies on this collection of information to evaluate whether an MA organization maintains a network of appropriate providers and facilities that is sufficient to provide adequate access to covered services based on the needs of the population served. In the collection of information, CMS explains that organizations must comply with the current CMS network adequacy criteria posted in the HSD reference file on CMS's website and updated annually. Our proposal aims to formalize the use of criteria posted in the HSD reference file by codifying and explaining the standards and, where necessary, the formulas used to calculate network adequacy standards (that is, provider/facility types, maximum time and distance standards, minimum provider/facility numbers). CMS will continue to use the HSD reference file as a means to communicate these standards to MA organizations, and therefore, this proposal requires no changes to the collection of information needed for CMS to assess network adequacy. The proposed provisions would not impose any new or revised information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements) or burden. Consequently, the provisions are not subject to the PRA.

We thank commenters in advance for their input on our proposed network adequacy policies.

F. Supplemental Benefit Requirements (§§ 422.100 and 422.102)

CMS has released guidance on supplemental benefits several times since April 2, 2018, including the 2019 Call Letter [89] and a subsequent HPMS memo [90] concerning the definition of 'primarily health related' with respect to supplemental benefits. Under a longstanding interpretation of the MA statute and regulations, CMS defines a mandatory or optional supplemental health care benefit as an item or service (1) not covered by original Medicare, (2) that is primarily health related, and (3) for which the plan must incur a non-zero direct medical cost. Only an item or service that meets all three conditions could be proposed as a supplemental benefit in a plan's PBP. We are proposing to codify this policy at § 422.102(c)(2)(ii) by setting forth these criteria as requirements that supplemental benefits must meet.

The current regulation text at § 422.100(c)(2) focuses on distinguishing between mandatory supplemental benefits and optional supplemental benefits. We are proposing to re-designate the substance of that current regulation text as new paragraphs (c)(2)(i)(A) and (B). We are proposing to codify our longstanding definition of supplemental benefits as three requirements that must be met by a supplemental benefit at paragraph (c)(2)(ii). In proposed paragraph (c)(2)(ii)(A), we would codify that a supplemental benefit must be primarily health related, using a standard discussed in more detail in this section of this proposed rule and with specific text to address SSBCI, discussed in more detail in section II.A. of this proposed rule. In proposed paragraph (c)(2)(ii)(B), we would codify that a MA organization must incur a non-zero direct medical cost in furnishing or covering the supplemental benefit to verify that the benefit is medically related, with specific text to address SSBCI, discussed in more detail in section II.A. of this proposed rule. Finally, in proposed paragraph (c)(2)(ii)(C), we would codify the requirement that the supplemental benefit is not covered by Medicare. By this, we mean that the supplemental benefit is not covered by Parts A, B or D. More generous or greater coverage of a Medicare Part A or Part B benefit—such as coverage of more inpatient days or coverage with lower cost sharing compared to Medicare—is a supplemental benefit. However, an MA plan may not cover a part D drug or reduce Part D cost sharing as an MA supplemental benefit. Under § 422.500, an MA plan that covers any Part D benefit must comply with the Part D regulations in part 423 and, therefore, must be a Part D sponsor of a Part D plan. In addition, § 422.266(b)(1) provides that an MA plan may use its rebates to buy down a Part D premium, including the premium for supplemental drug coverage described at § 423.104(f)(1)(ii).

1. Primarily Health Related

As discussed in the 2019 Call Letter and April 2018 HPMS memo, CMS currently interprets ''primarily health related'' as meaning that the item or service is used to diagnose, compensate for physical impairments, acts to ameliorate the functional/psychological impact of injuries or health conditions, or reduces avoidable emergency and healthcare utilization. Using this interpretation, CMS has provided MA plans with flexibility in designing and offering supplemental benefits that may enhance beneficiaries' quality of life and improve health outcomes. We are proposing to codify this definition of a supplemental benefit at § 422.102(c)(2)(ii)(A).

Examples of supplemental benefits include: Dental, vision, adult day health services, home-based palliative care, in-home support services, support for caregivers of enrollees, stand-alone memory fitness, expanded home & bathroom safety devices & modifications, wearable items such as compression garments and fitness trackers, over-the-counter items, and expanded transportation. A supplemental benefit is not primarily health related under this definition if it is an item or service that is solely or primarily used for cosmetic, comfort, general use, or social determinant purposes. Also, to be primarily health related, the benefit must focus directly on an enrollee's health care needs and should be recommended by a licensed medical professional as part of a care plan, if not directly provided by one. Enrollees are not currently required to get physician orders for supplemental benefits (for example, OTC items) and requiring it now would impose new restrictions on MA plans and potentially cause large administrative burden and interruptions in care. Therefore, CMS

[89] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.*

[90] *https://hpms.cms.gov/hpms/upload_area/NewsArchive_MassEmail/000011202/HPMS%20Memo%20Primarily%20Health%20Related%204-27-18.pdf.*

uses the ''recommended'' standard as part of interpreting and applying this component of the definition of supplemental benefit. We note that supplemental benefits must also be medically appropriate to be primarily health related; if a service or item is not medically appropriate, it is not primarily health related. This is consistent as well with our longstanding guidance in Chapter 4, section 30.2, of the Medicare Managed Care Manual that supplemental benefits that extend Part A or Part B benefits must be medically necessary. We will continue our current interpretations and guidance in codifying existing policy on this issue.

We note that the BBA of 2018 amended section 1852(a)(3) of the Act to permit MA plans to offer additional supplemental benefits for chronically ill enrollees (SSBCI) in contract year 2020. We discuss implementation of that legislation in section II.A. of this proposed rule. The new legislation permits supplemental benefits that are not primarily health related, but limited these benefits to chronically ill enrollees, using a statutory definition. It added new supplemental benefit options for the chronically ill that are in addition to the existing supplemental benefit options available to all MA enrollees effective contract year 2020. The expansion of supplemental benefits for chronically ill enrollees does not affect the expanded scope of the primarily health related supplemental benefit standard discussed here because supplemental benefit standard requires more than just a reasonable expectation of improving overall health and instead requires supplemental benefits to address specific illnesses and/or injuries.

2. Uniformity Requirements

As explained in the April 2018 final rule (83 FR 16440, 16480–85), CMS determined that providing access to supplemental benefits that are tied to health status or disease state in a manner that ensures that similarly situated individuals are treated uniformly is consistent with the uniformity requirement in the MA regulations. We solicited comments on this reinterpretation and finalized it in that prior rulemaking. In response to those comments and our further consideration of this issue, we provided guidance to MA organizations in both the April 2018 final rule and a subsequent HPMS memo [91] released April 27, 2018. We are proposing now to codify this reinterpretation specifically in regulation text at § 422.100(d)(2)(i).

The regulatory requirement that MA plans provide uniform benefits implements both section 1852(d) of the Act, which requires that benefits under the MA plan are available and accessible to each enrollee in the plan, and section 1854(c) of the Act, which requires uniform premiums for each enrollee in the plan. Previously, we required MA plans to offer all enrollees access to the same benefits at the same level of cost sharing. In 2018, in issuing a final rule and guidance for contract year 2019, we determined that these statutory provisions and the regulation at § 422.100(d) meant that we had the authority to permit MA organizations the ability to reduce cost sharing for certain covered benefits, including lower deductibles, and offer specific tailored supplemental benefits for enrollees that meet specific medical criteria, provided that similarly situated enrollees (that is, all enrollees who meet the medical criteria identified by the MA plan for the benefits) are treated the same. In addition, we stated that our interpretation means that there must be some nexus between the health status or disease state and the specific benefit package designed for enrollees meeting that health status or disease state. We propose to redesignate (d)(2) as (d)(2)(i) and add new paragraph (d)(2)(ii) to specifically state that MA organizations may reduce cost sharing for certain covered benefits, including lower deductibles, and offer specific tailored supplemental benefits for enrollees that meet specific medical criteria, provided that similarly situated enrollees are treated the same and that there is some nexus between the health status or disease state and the tailored benefits. We review benefit designs to make sure that the overall impact is non-discriminatory and that higher acuity, higher cost enrollees are not being excluded in favor of healthier populations. This provision codifies already existing guidance and practices and therefore is not expected to have additional impact above current operating expenses.

G. Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134 and Subpart V)

CMS authorized MA organizations, including those offering a Medicare Medical Savings Account (MSA) plan option, to offer rewards and incentives (R&I) programs in a regulation adopted in 2014 (79 FR 29956, May 23, 2014). We briefly review the history of that rulemaking and our policies and goals for authorizing R&I programs. We relied on our authority under sections 1856(b)(1) and 1857(e)(1) of the Act to adopt the regulation; in addition, several of the provisions of the regulation, such as the anti-discrimination requirement, were consistent with statutory provisions governing the MA program. We adopted the regulation that authorized Part C R&I programs for a number of reasons. In some cases, MA organizations wished to extend rewards and incentives already offered to their commercial members to their Medicare enrollees; and many MA organizations wished to sustain their current R&I programs as well as stay competitive with other MA organizations with comparable offerings. Further, there was some evidence to suggest that health-driven reward and incentive programs may lead to meaningful and sustained improvement enrollee health behaviors and outcomes.[92]

Over the years we have also been asked by many plans to clarify how to start an R&I program. Our experience has shown that most R&I programs fall into the following four areas:

(i) Specified use of plan benefits, for example, rewards provided for obtaining preventive benefits at specified intervals;

(ii) Following a specified program that promotes exercise and/or good nutrition;

(iii) Participating in specified programs that educate on health matters and/or self-management of nutrition and exercise;

(iv) Specified utilization of plan resources such as hotlines, patient portals, and similar items that facilitate promotion of health.

Having reviewed the history of the program, we next describe its current state. Over the past 5 years, MA R&I programs have grown. We have benefitted greatly from partnership with our stakeholders who continually provide fresh and innovative ideas. We continue to encourage MA organization flexibility in rewards and incentives that is nonetheless consistent with the basic protections and parameters in the current regulation. Over the past 5 years we have also received many inquiries about how the regulation applies to specific R&I programs, including questions about the types of rewards that may be offered, types of health related activities that may be rewarded, and targeting R&I programs to specific

[91] *https://hpms.cms.gov/hpms/upload_area/News Archive_MassEmail/000011207/HPMS%20Memo %20Uniformity%20Requirements%204-27-18.pdf.*

[92] Ali Shirvani-Mahdavi, Ph.D. & Melissa Haeffner Ph.D., *Rewarding Wellness: The Science Behind Effective Wellness Incentive Programs* (2014).

disease states. To address these questions and based on our experience implementing the current regulation, we are proposing to amend § 422.134 to codify the guidance we have given, unify principles governing MA rewards and incentive programs, clarify the requirements of the regulation, and clarify flexibilities available to MA organizations under the regulation.

Under our proposal, we would move the substance of current paragraph (a) to new paragraph (c)(1)(iii). New paragraph (c) deals with the requirements of the target activity and therefore the current paragraph (a) which enumerates three categories promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources is moved to paragraph (c) since being health related is a requirement of the target activity. In this way the purposes and goals of R&I programs, to improve health incomes, is still mentioned in the regulatory text albeit as an attribute of target activities.

We are proposing a new paragraph (a) to define several terms used in § 422.134. We propose to define a ''Reward and Incentive program'' as a program offered by an MA organization which allows qualified individuals (as defined later in this section) to voluntarily perform target activities in exchange for which the plan provides reward items. This definition of R&I program replaces certain aspects of current paragraph (a). The health related requirements in current paragraph (a) are requirements on target activities (not on for example reward items) and hence these health-related requirements were moved and placed in new paragraph (c). We propose to define ''target activity'' as that activity for which the reward is provided to the enrollee by the MA plan. We propose to define the term ''reward item'' as the item furnished to an enrollee who performs a target activity as specified by the plan. Further, we propose to revise the regulation to explicitly provide that when referring to the entire R&I program offered by a plan (that is, the target activity, its reward, and any requirements) the following terms are synonymous: ''reward and incentive program,'' ''reward(s) program'', ''incentive program'', and ''R&I program''. We also propose to clarify that when referring to the particular items used as rewards the following terms are synonymous: ''reward(s)'', ''incentive(s)'', ''R&I'', and ''rewards and incentives''. Similarly, we propose that the terms ''reward item'' and ''incentive item'' are synonymous. We are also proposing a definition for the term ''qualifying individual'' as that term is used throughout proposed § 422.134. This term has different meanings depending on whether the context of the target activity is a plan-covered health benefit or not: (1) If the target activity is not a plan-covered benefit (for example adherence to a particular diet), the term means a plan enrollee who satisfies the plan criteria to participate in that target activity; and (2) If the target activity is a plan-covered benefit (for example obtaining a mammograms), the term means a plan enrollee who qualifies for the target activity and satisfies all plan criteria to participate in the target activity.

For clarity, we are proposing to reorganize the order and structure of how the regulation addresses the requirements for R&I programs. We are proposing to address the substance of current paragraph (b) regarding non-discrimination and current paragraph (c) regarding prohibitions and requirements in new text in the revised regulation. As part of our reorganization, we are proposing to address the requirements for target activities in paragraph (c) and the requirements for reward items in paragraph (d).

In paragraph (b) we propose to state that MA programs are allowed to offer R&I programs consistent with the requirements of the section. This allowance is in current paragraph (a). Since the majority of (a) has been moved to new paragraph (c) it is important to explicitly state the allowance for MA plans to offer R&I programs.

Proposed paragraph (c) sets forth the requirements for a target activity to be used in an R&I program; compliance with these requirements is necessary in order for the MA organization to provide a reward item to a qualifying individual for participating in the activity. We propose to organize paragraph (c) by whether the proposed standard is something the target activity must do (or meet) or is something the target activity must not do. Additionally, proposed paragraph (c) will incorporate the current health-related requirements of current paragraph (a), since, although health improvement is the goal of the R&I program, these health-requirements are requirements in target activities (not for example in reward items) and therefore should be listed in (c).

Proposed paragraph (c)(1)(i), requires the qualifying individual be directly involved and perform the target activity. CMS recognizes there is growing involvement of caregivers, such as immediate family, with enrollees. However, the purpose of R&I programs is to provide a way for plans to influence positive behavioral changes of qualifying individuals through the performance of target activity designed to achieve at least one of the stated goals under (c)(1)(iii). Therefore, under our proposal, the qualifying individual must perform the activity and not the caregiver or other third party individual. Similarly, we propose in paragraph (d)(1)(i) that the reward item must be a direct tangible benefit to the enrollee. This means that the reward item may not be offered to or for the benefit of caregivers or other third party individuals. For example, under these proposed provisions, an MA organization may not offer a gift card to caregiver (such as family members) that attend an educational class about services provided to enrollees.

We are proposing a new paragraph (c)(1)(ii) to require that a target activity must be specified, in detail, as to the level of completion needed in order to qualify for the reward item. We are proposing (c)(1)(ii) as a replacement for the current requirement (at paragraph (c)(1)(i)) that a reward be available only in connection with an entire service or activity as it has caused confusion and generated numerous inquiries over the past 5 years. The current formulation, ''entire'' activity, could be misread that a plan could not simultaneously reward both the completion of a multi-part activity and one of its components. That was not our original intent. Rather, the intent was to require specificity: If the plan only specified the entire activity then it could not reward completion of a component activity; but if the plan wanted to reward both the completion of the entire activity as well as one of its components (possibly with different rewards) then it could do so provided it specified in detail the level of completion needed in order to qualify for the reward item.

A typical application of this principle occurs with an R&I program rewarding multi-session health management classes (for example weight management). The proposed formulation allows the following: (1) An MA organization targets an 8 session weight management class and provides rewards to those enrollees who complete the entire 8 sessions; and (2) An MA organization targets an 8 session weight management class and provides a separate reward for each session enrollees attend. Both of these are permissible because of how the plan (or R&I program) defines the completed activity or what is an entire activity to be completed. To allow plan flexibility we are proposing to clarify that an MA organization must specify, in detail, the

level of completion of a target activity in order for the qualifying individual to receive the reward item. Each scenario discussed previously would be permissible under our proposal provided the MA organization has clearly indicated completion criteria. We believe our proposed text at (c)(1)(ii) clarifies our desired policy. Therefore, we propose that the language at current (c)(1)(i) be eliminated and be replaced by the proposed (c)(1)(ii).

We propose to add paragraph (c)(1)(iii) which moves the health-related requirements currently in paragraph (a). These health-related requirements encompass the goals of the R&I program, that is, the R&I program should include at least one of three health-related requirements as its stated goal: (1) The improvement of health; (2) prevention of injures and illness or (3) promotion of efficient use of health care resources. The target activity must be designed to achieve at least one of the health-related requirements. To illustrate this, we note that (c)(1)(iii)(B), preventing injuries and illness, would allow an MA organizations to reward wearing seat belts. The wearing of the seat belt is considered health related since its purpose is to prevent injury. Paragraph (c)(1)(iii)(C), promoting efficient use of health care resources, would allow MA plans to reward use of online secure web portals that track exercise or weight management.

Next, we propose a new paragraph (c)(2) to list prohibitions connected with target activities. Proposed paragraph (c)(2)(i) specifies that a target activity must not be related to Part D benefits. In other words, Part D benefits may not be targeted for rewards. Our regulations at § 422.134 are only applicable to the MA program, therefore activities that are tied to Part D benefits may not be part of an R&I program under § 422.134. Examples of targeting a Part D benefit or tying a reward to Part D benefits that are prohibited under this proposed regulation text include providing a reward based on filling a prescription, and medication adherence.

We propose new (c)(2)(ii) to prohibit discriminatory use of R&I programs against enrollees. The current regulations prohibit discrimination at (b)(1) and (2) and (c)(2)(ii) but we are concerned that the current regulation text does not adequately address several issues specific to the provision of rewards and incentives. Paragraph (c)(2)(ii) proposes to supplement the general anti-discrimination prohibitions applicable throughout the MA program (currently in § 422.134(b)(1)) by proposing three new anti-discrimination requirements. These three requirements are in response to inquiries CMS has received.

An MA organization may design an R&I program that targets a specific illness or disease state. There are many cases where the target activity of an R&I program is a healthcare service predominately available to or medically necessary for a specific group, such as a reward for enrollees who obtain mammograms at recommended periodic intervals. For example, a high statistical frequency of only women (who are the primary recipients of mammograms) receiving rewards would, in and of itself, raise concerns of possible discrimination. To avoid this possible complication, and to facilitate an environment in which plans may propose R&I programs to address the need for target activities such as mammograms we propose three new requirements designed to assure that R&I programs are not discriminatory.

First, we propose to require R&I programs be uniformly offered to any qualifying individual at new paragraph (c)(2)(ii)(A). We also propose to add to paragraph (a) (''Definitions'') that in the context of a discussion of a plan-covered health benefit or service, the term ''qualifying individual'' means any plan enrollee who would qualify for coverage of the benefit and also satisfies any other plan criteria to participate in the target activity. By this, we mean to be clear that a target activity that is a covered benefit would be medically necessary for the particular enrollee who is seeking to receive the reward and that other conditions on coverage by the MA plan are met. Some illustrations of the use of the term qualifying individual are as follows:

(1) A plan that rewards mammograms can deny, without violating the discrimination prohibition under this proposed regulation, a reward to a man without gynecomastia who obtained a mammogram. The reason for the denial is that mammograms by males without gynecomastia are not plan covered because the mammogram is not medically necessary;

(2) A plan that rewards mammograms can deny, without implicating the anti-discrimination prohibition in this proposed regulation, a reward to a woman not at risk and in good health for obtaining a mammogram one month after previously obtaining a mammogram. The reason for the denial is because the woman is not a qualifying individual for this mammogram since the plan's coverage criteria for Original Medicare benefits must be consistent with Original Medicare and the Original Medicare frequency requirements for coverage of mammograms has not been met; therefore this mammogram taken one month after a previous mammogram does not meet the criteria for a plan-covered benefit.

(3) A plan would reward a man suffering from gynecomastia for obtaining a mammogram since this is a plan-covered service for this individual.

By proposing to require R&I programs be formulated in terms of any qualifying individual, we hope to broaden the rewards and incentives available without permitting discriminatory activity. To avoid misunderstanding we emphasize that this requirement is in addition to all other anti-discrimination prohibitions in this regulation and in the MA program.

The second anti-discrimination requirement we are proposing is related to the requirement currently in (b)(2) that all members may earn rewards. We intended this current regulatory provision to require accommodations for target activities. We continue to believe that providing accommodations to enrollees so that there is fair and equitable ability to earn a reward is important. We are proposing, at paragraph (c)(2)(ii)(B), to require the MA organization to provide accommodations to qualifying individuals who would otherwise be eligible for the reward but are unable to perform the target activity. We intend an accommodation to be something such as permitting the enrollee to engage in a comparable activity in a manner that satisfies the intended goal of the target activity or providing additional access to the target activity for the enrollee. For example, if a target activity encourages individuals with high blood pressure to go to a gym, we propose that accommodations must be made for institutionalized enrollees are not able to access a gym such that they are still engaged in a comparable activity with the same goal, namely engaging in physical activity for purposes of blood pressure management. Similarly, if the MA plan tracks participation in a target activity in a way that involves web access, we propose that accommodations must be made for enrollees without web access, such as by permitting other means to prove participation. We solicit comments from our stakeholders if this requirement of accommodations as formulated is sufficient and ask if some restrictions should be included in the regulatory requirement. To assist in solicitation of comments on the need for accommodations, we note that this proposed requirement for accommodation is intended to be consistent with requirements of HIPAA

wellness programs [93] and at the Appendix to 29 CFR 1630.14(d).

The third anti-discrimination requirement we are proposing addresses the achievement of desirable measurable health statuses. We are proposing to add, at paragraph (c)(2)(ii)(C), a specific requirement that MA plans must not design a R&I program based on the achievement of a specific health status measurement. CMS recognizes that MA organizations designing R&I programs are interested in achieving desirable, measurable health outcomes, such as achieving a desirable blood pressure or target weight. However, if the target activity is formulated this way, it would discriminate against enrollees based on health status. There may be individuals who will never reach a specific blood pressure level or target weight due to circumstances beyond their control (for example, medication side effects). For plans wishing to create such R&I programs, we propose that target activities must be formulated without reference to achieving a specific outcome and focus on a desired behavior instead, such as checking one's blood pressure or exercising regularly. Thus, we propose that the MA organization must not tie or limit the availability of the reward to the achievement of a health status measurement. Under this proposal, an MA organization may reward behaviors such as taking and reporting measurements at particular intervals, undergoing lab tests providing such measurements, or other activities reflecting a motivation to reach desirable measurements of health status or desirable health outcomes.

In summary, we proposed in paragraph (c)(2)(ii) to set out specific anti-discrimination requirements for an R&I program by requiring the program be offered to all qualifying individuals, making accommodations for otherwise qualifying individuals, and be based on enrollee behaviors rather than on desired measurements of health outcomes. As indicated, we believe this approach simultaneously guarantees necessary protections, allows maximum MA organization flexibility, and provides clarity. Finally, we also make explicit that anti-discrimination is a requirement of the entire MA program and these three requirements are in addition to other requirements. This statement is indicated in (c)(2)(ii) by cross-referencing the new proposed (g)(1) which mentions the general requirement of anti-discrimination throughout the MA program.

We believe the new proposed paragraph (c) unifies all current guidance on target activities, clarifies appropriate distinctions, and will facilitate MA organizations in their quest for new innovative designs. We solicit comments whether additional specific prohibitions or requirements for target activities are necessary to meet our described goals for revising the authority for MA organizations to establish and use R&I programs.

We propose a new paragraph (d) address requirements and prohibitions for reward items. Our proposal summarizes and clarifies existing CMS guidance on reward items. We propose to divide new paragraph (d) into three paragraphs: (d)(1) Addressing requirements of reward items, (d)(2) addressing prohibitions associated on reward items, and (d)(3) addressing allowances and flexibilities for reward items.

New paragraph (d)(1)(i) reflects the principles of current paragraph (b)(2); we propose to require that the reward items be offered uniformly to any qualifying individual who performs the target activity. As indicated earlier, the term qualifying individual is defined in new paragraph (a). New paragraph (d)(1)(ii) codifies subregulatory guidance; we propose that the reward item should be a direct tangible benefit to the qualifying individual (as defined in paragraph (a)) who performs the target activity. In a situation where it was suggested that an R&I program provide charitable donations as a reward for enrollees fulfilling a target activity, we denied approval of the R&I program because the charitable donation was not a direct tangible benefit to the enrollee. We believe that the ''charitable donation on behalf of the enrollee'' was somewhat misleading because the charity, not the enrollee, actually benefitted from the reward. In new paragraph (d)(1)(iii), we propose to require rewards be provided, such as through transfer of ownership or delivery, to the enrollee in the contract year in which the activity is completed, regardless of whether the enrollee is likely to use the reward item after the contract year. For example, if an enrollee earns a $25 gift card as a reward in late December, as long as the MA organization transfers that gift card to the enrollee before the contract year is over, the MA organization has fulfilled its obligation under this proposed provision. Consequently, since the enrollee now owns the reward item the plan would not be allowed to erase the card or invalidate the reward in the next contract year because the proposed provision requires transfer of ownership to the enrollee, who would retain the right to use the card whenever he or she wants. We believe that this is an important beneficiary protection to ensure that rewards are timely provided to the enrollee. Provision of the reward item to a third party or caregiver would be prohibited under this regulation.

Proposed new paragraph (d)(2) summarizes prohibitions connected with reward items. Proposed paragraphs (d)(2)(i) prohibits reward items consisting of cash, cash equivalents or monetary rebates (current paragraph (c)(2)(i)). In proposed (d)(2)(i)(A) and (B), we adopt the definition of ''cash equivalent'' formulated by the Office of the Inspector General (OIG) (81 FR 88368, December 7 2016), which defines ''cash equivalent'' to be items convertible to cash (such as a check) or that can be used like cash (such as a general purpose debit card, but not a gift card that can be redeemed only at certain stores, certain store chains, or for a specific category of items like a gasoline gift card).

Current paragraph (c)(1)(iii) says that reward items must ''have a monetary cap as determined by CMS,'' However, over the past five years, CMS has never calculated or published such a cap. We are therefore replacing this requirement with paragraph (d)(2)(ii) which requires that a reward item have a value that does not exceed the value of the target activity itself. This new proposed cap, the value of the target activity, is objectively determined and does not require a CMS determination.

We propose to codify a new paragraph (d)(2)(iii) to prohibit a target activity from involving elements of chance, for example lotteries. We believe this protects enrollees who may be misled by the chance of winning when such chance may be very small.

Plans know that items such as tickets allowing entry to events with a cost or discount coupons for specific items allowing purchases at reduced prices are allowed for rewards under our current guidance. Furthermore, paragraph (d) adequately outlines the requirements for rewards. In new paragraph (d)(3) we propose to present two additional examples of permissible reward items for a target activity. These two examples have arisen from plan inquiries.

In new paragraph (d)(3)(i) we codify current practice to allow reward items to consist of points or tokens which can be redeemed for tangible items. This is unlike a lottery where you only win if you obtain a certain event (like a number coming up) with the winning

[93] *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/publications/caghipaaandaca.pdf.*

event having a small probability. Here, the value of the point and token is determined and known in advance. More specifically, it is known in advance that with so many points you can redeem them for tangible items listed by the plan. There is no element of chance. The redeemed item, however, must be a tangible and must otherwise comply with all other R&I program requirements.

In new paragraph (d)(3)(ii) we codify the current practice of allowing gift cards for reward items with the added qualification that a gift card is only permissible if it is designated for specific stores, specific store chains, or for specific categories of items or services (such as a gasoline card). There is no requirement that the store, store chain, or category of items or services be health related. Additionally, CMS acknowledges receiving inquiries from plans in states where a gift card must be converted to cash by a retailer if it only has a minimal value. Here, we clarify an MA plan may still offer gift cards as a reward in states with such laws because when the gift card was given to the enrollee it could only be used in certain locations or for certain purposes. We consider this allowable because the gift card is not immediately convertible to cash. The fact that later on it may be worth a nominal amount does not retroactively cancel its non-cash-equivalent status.

We believe the restructured paragraph (d) provides greater clarity, unifies all known guidance, and facilitates MA organizations seeking innovation. We solicit comment on our proposed standards for the reward items that are used in R&I programs authorized by § 422.134. Specifically, we seek comment whether our requirements need to be further clarified or if additional standards or examples are needed as enrollee protections.

As part of our reorganization, we are proposing to move the marketing requirements that are currently addressed at § 422.134(c)(2)(ii) to new provisions in proposed subpart V of 42 CFR part 422, which are discussed in section VI.H. of this proposed rule. We propose to codify, at new paragraph (e) of § 422.134, a requirement that MA organizations, in connection with an R&I program offered under § 422.134, must comply with all communications and marketing requirements as specified in subpart V of part 422.

We are also proposing, at new paragraph (f), that an MA organization must make information available to CMS upon request about the form and manner of any R&I programs the MA organization offers and any evaluations of the effectiveness of such programs. We solicit comment on this proposal and whether specific reporting should be required to support program monitoring and oversight.

Finally, we are proposing to add paragraphs (g)(1) through (3) for miscellaneous provisions from the current regulation. New paragraph (g)(1) proposes to codify the general requirement of anti-discrimination, applicable throughout the MA program (current paragraph (b)(1)). Additionally, the existing requirement that the reward and incentive program comply with all relevant fraud abuse laws including, when applicable the anti-kickback statute and civil monetary penalty prohibiting inducements to beneficiaries is moved to (g)(1).

Proposed new paragraph (g)(2) codifies that violations of R&I regulatory requirements can lead to sanctions (current paragraph (b)(3)). We note that current paragraph (b)(3) discusses sanctions in the context of violations of anti-discrimination. However, sanctions could also be imposed if, for example, an MA organization promised an R&I program (not a benefit) and then reneged on its commitment. This would violate § 422.752(a)(5) and (11) since the plan falsely communicated to enrollees and made misleading marketing about its R&I program. It also might violate (a)(4) since such false communications might be construed as discouraging enrollment. By proposing to codify the sanction provision as a stand-alone provision in proposed new paragraph (g), we clarify our intentions.

We are also proposing to codify, at new paragraph (g)(3), current guidance that an R&I program is not a benefit. We also are proposing, at new paragraph (g)(3)(i), that the MA organization must include all costs associated with the reward and incentive program as an administrative cost and non-benefit expense in the bid for the year in which the reward and incentive program operates. Similarly, we are proposing, at new paragraph (g)(3)(ii), that disputes on rewards and incentives must be treated as a grievance under § 422.564.

We are also proposing, at paragraph (g)(4), to add a prohibition on mid-year changes to an R&I program. This because R&I programs must be included in the plan bid each year as a non-benefit expense. However, we also believe this is an important beneficiary protection and will ensure that beneficiaries are aware when they enroll in a plan what R&I may be available to them.

For the most part, our proposal to revise § 422.134 unifies and codifies existing guidance. We therefore do not believe this provision creates new cost or savings impact for the MA program.

H. Requirements for Medicare Communications and Marketing (§§ 422.2260–422.2274; 423.2260–423.2274)

Sections 1851(h) and (j) of the Act provide a structural framework to define how Medicare Advantage (MA) organizations may market to beneficiaries and direct CMS to adopt additional standards related to review of marketing materials and limitations on marketing activities. Section 1860D–1(b)(1)(B)(vi) of the Act directs that the Secretary use rules similar to and coordinated with the MA rules at section 1851(h) for approval of marketing material and application forms for Part D plan sponsors. Section 1860D–4(l) of the Act applies certain prohibitions under section 1851(h) to Part D sponsors in the same manner as such provisions apply to MA organizations. CMS has adopted regulations related to marketing by MA organizations and Part D sponsors in § 422.111; 42 CFR part 422, subpart V; § 423.128; and 42 CFR part 423, subpart V; these regulations include the specific standards and prohibitions in the statute as well as additional standards and prohibitions promulgated under the statutory authority granted to the agency. Additionally, under the implementation of section 1876(c)(3)(C) of the Act through regulations at § 417.428, the marketing requirements in subpart V of part 422 apply to section 1876 cost plans as well. CMS has long provided sub-regulatory guidance, building upon and intended to provide further interpretation and guidance for these regulations, in the form of a marketing manual titled the Medicare Communications & Marketing Guidelines (MCMG), previously known as the Medicare Marketing Guidelines.

CMS now proposes to codify the additional guidance contained in the MCMG by combining the guidance set forth within the MCMG with the current regulations. In doing so, some reorganization and renumbering of existing regulations is necessary, as the proposed revised regulations are organized according to the topics in the MCMG, rather than fitting into the existing regulation order and flow, as we believe plans are more accustomed to the detailed additional guidance in the MCMG and we intend for the proposed regulations to closely mirror this long-standing sub-regulatory guidance. As part of the reorganization, the proposal in some cases also reorganizes existing regulations, even though CMS does not intend to change

the policy expressed in those regulations. To be clear, the policies we are proposing to codify are not new to the industry; they are already in place in the MCMG and were developed over time in concurrence with industry comments weighing in on the best way to implement marketing requirements in the context of operating the MA, Part D, and cost programs, and plans are accustomed to conforming to these policies. Because this proposal is applicable to MA organizations, Part D plan sponsors and cost plans, we refer to the regulated entity in this proposed rule as a ''plan'' and intend this term to refer to all three of these entities.

The first of the policies that CMS intends to codify, in §§ 422.2260 and 423.2260, is the guidance related to the definitions of ''marketing'' and ''communications,'' as well as additional definitions from the MCMG. CMS has amended and expanded our marketing regulations for both the MA and the Part D programs at 42 CFR parts 422 and 423, subparts V, respectively, several times since their original implementation, and have provided additional sub-regulatory guidance in the MCMG each time, to ensure beneficiaries receive the necessary information to make informed choices. Recently, in the April 2018 final rule, we updated 42 CFR parts 422 and 423, subpart V, including establishing new definitions for communications materials and activities and marketing materials and activities in 42 CFR 422.2260 and 423.2260, which set out the scope of materials and activities subject to our regulations. In the 2019 MCMG, we provided additional guidance that further clarified these definitions based on our interpretation that the regulations used ''intent'' and ''content'' as the deciding factors for when a communication activity or material was marketing.

We now propose to codify the additional guidance we provided in the MCMG and revise the regulation text at §§ 422.2260 and 423.2260 to align more closely with our interpretation. Specifically, we propose, at §§ 422.2260 and 423.2260, that ''marketing'' means communications materials and activities that meet certain standards for intent and content that we enumerate in the regulation text. For the intent standard, we use the same intent language that is in the current regulation with a technical change to separately list out two different intent standards (paragraphs (1)(ii) and (iii) in the proposed definition of marketing) that were previously combined in one paragraph (paragraph (3) in the current definition of marketing materials). As previously practiced, when evaluating the intent or an activity or material, as previously, CMS will consider objective and contextual information (for example, audience, timing, etc.) and is not limited by the plan's statements about its intent.

Under the content standard, we propose in the revised regulations to state affirmatively what must be included for a communications activity or material to be a marketing activity or material, rather than stating what is excluded (as the current regulation does). The first two types of content listed (paragraphs (2)(i) and (ii) under the definition of marketing) are derived from the current regulation (although we specify ''premiums,'' as in the MCMG). The third type of content we enumerate is information on rewards and incentives programs, as we wanted to be clear that while rewards and incentives themselves are not a benefit, they are used as a means of prompting a beneficiary to use a specific benefit, and therefore our policy has been that information on rewards and incentives fall within the definition of marketing. We now propose to explicitly list this as a type of content to avoid any confusion, so that plans continue to be aware that in providing any information on rewards and incentives they should follow the same requirements as for other marketing. We also propose to make some revisions to §§ 422.2260 and 423.2260 to streamline the definitions, such as by removing the list in the current regulation of examples of materials (for example, brochures; posters). We no longer believe this list of examples is necessary, as we have consistently evaluated whether a material is marketing based on intent and content, and not based on its particular form. Additionally, we propose to combine the definitions for ''communications'' and ''communications materials,'' as well as ''marketing'' and ''marketing materials''; this will streamline the definitions section and be consistent with how we have interpreted the current regulations that both activities and materials are subject to the same intent and content standards. We also propose to state explicitly in the definition of ''communications'' that communications activities and use of materials are those ''created or administered by the MA organization or any downstream entity.''

Finally, we propose to codify at §§ 422.2260 and 423.3360 additional definitions that apply to plan marketing. Specifically, we propose to define ''advertisement (ad),'' ''alternate format,'' ''banner,'' ''banner-like advertisements,'' and ''Outdoor Advertising (ODA).'' These definitions are familiar terms that CMS has previously defined and used throughout the MCMG; while we make some technical and clean-up edits primarily to reflect their new form as regulation text, rather than manual guidance, our proposal does not change these definitions in a substantive manner. With the codification of much of the rest of the MCMG, it becomes important to also codify these definitions, which are used throughout the MCMG and are now used throughout the proposed regulations.

We next propose to codify in new §§ 422.2261 and 423.2261 requirements for plans to submit certain materials to CMS for review, the process for CMS review, and the standards by which CMS will perform the review. These requirements are currently found in §§ 422.2262, 422.2264, 423.2622, and 423.2264, as well as in section 90 of the MCMG, which builds upon those sections and includes more detailed operational instructions to plans regarding submission, review, and distribution of marketing materials (including election forms). In particular, we propose at §§ 422.2261(a)(1) and 423.2261(a)(1) that the Health Plan Management System (HPMS) is the primary system of record and the mechanism by which CMS collects and stores submitted plan materials for review and evaluation. Additionally, we propose to codify, at §§ 422.2261(a)(2) and 423.2261(a)(2), our current policy that only plans can submit materials to CMS for review and approval for use. We also propose to specify that this policy prohibits third parties/downstream entities (as they currently are) from submitting materials directly to CMS. Additionally, in new §§ 422.2261(d) and 423.2261(d), we propose to codify that CMS reviews submitted materials for compliance with all applicable requirements in §§ 422.2260 through 422.2267 and §§ 423.2260 through 423.2267, respectively, and that the benefit and cost information is an accurate reflection of what is contained in the MA organization's bid. These standards are consistent with our current policy and how we review marketing materials.

We next propose to codify general standards for plan communications, including requirements related to product endorsements and testimonials and standardization of certain materials (specifically, certain telephone numbers and material IDs) at proposed new §§ 422.2262 and 423.2262. These general standards are currently found in §§ 422.2268(a) and 423.2268(a), which

also include some examples of what plans may not do. While our proposal retains the general standards prohibiting MA plans from misleading, confusing, or providing inaccurate information to current or potential enrollees, we are expanding the lists of examples of what plans may not do (in paragraph (a)(1)), and incorporating examples of what plans are explicitly permitted to do (in paragraph (a)(2)), all consistent with our current guidance in section 30 of the MCMG.

We also propose to codify at §§ 422.2262(b)(2) and 423.2262(b)(2) requirements regarding endorsements and testimonials currently found in section 30.8 of the MCMG. We propose to explicitly note in §§ 422.2262(b)(1) and 423.2262(b)(1) that, consistent with our current policy, product endorsements and testimonials may take different forms. We also propose to codify in §§ 422.2262(c) and 423.2262(c) requirements currently found in section 30 of the MCMG related to including telephone numbers (specifically, customer service numbers and 1–800–MEDICARE) in materials. These additional parameters for how telephone numbers are communicated and included in communications and marketing ensure that beneficiaries get useful and accurate information. And finally, we propose to codify requirements related to standardized material identification, currently found in section 90.1 of the MCMG, in §§ 422.2262(d) and 423.2262(d).

We next propose to codify, at §§ 422.2263 and 423.2263, requirements related to how plans may conduct marketing, which is explicitly specified as a subset of communications and therefore also subject to the requirements proposed in §§ 422.2262 and 423.2262. First, we are proposing to clarify that October 1 is the date plans may begin marketing for the upcoming plan year. This is consistent with the longstanding guidance, but we believe that the current regulation with this date (at §§ 422.2274(b)(4) and 423.2274(b)(3)) lacks specificity on this point. We therefore propose to codify this long-standing policy in §§ 422.2263(a) and 423.2263(a). We also codify, in §§ 422.2263(b) and 423.2263(b), a list of examples of what plans may not do in plan marketing. This list is drawn from existing §§ 422.2268(b), 423.2268(b) and section 40.1 of the MCMG, although we have made some technical clean-up edits. We note that a number of the prohibitions that are currently stated in §§ 422.2268(b) and 423.2268(b) are codified elsewhere in these proposed regulations where they topically fit under the new subpart organization. Finally, at § 422.2263(c), we codify requirements related to marketing of Star ratings that are currently found in section 40.6 of the MCMG.

We next propose to codify, at revised 42 CFR 422.2264 and 423.2264, requirements related to plan contact with Medicare beneficiaries and a beneficiary's caregivers. As used in this proposed regulation, ''beneficiary contact'' includes all outreach activities to a beneficiary or a beneficiary's caregivers by the plan or its agents and brokers. First, in 42 CFR 422.2264(a)(1) and 423.2264(a)(1), we propose to codify the policy for when unsolicited contact is permitted, including direct mail and email which are currently found in the MCMG. Under 42 CFR 422.2264(a)(2) and 423.2264(a)(2), we propose to codify the rules for when unsolicited direct contact with beneficiaries is and is not permitted. Currently, §§ 422.2268(b)(13) and 423.2268(b)(13) explicitly prohibit plans from soliciting door-to-door or engaging in other unsolicited contact and our guidance in section 40.2 of the MCMG addresses this prohibition with additional detail about activities we consider and do not consider to be unsolicited contact. Additionally, under 42 CFR 422.2264(a)(2) and 423.2264(a)(2) we also propose to codify that unsolicited direct messages from social media platforms are also prohibited, which is currently housed in section 30.6 of the MCMG. We also propose to clarify that plans may contact their current members (including those individuals enrolled in commercial plans who are becoming eligible for Medicare) regarding plan business. Finally, in §§ 422.2264(c) and 423.2264(c), we propose to codify requirements regarding events (such as meetings) with beneficiaries, currently found in section 50 of the MCMG; in doing so, we include some additional statements consistent with our current policies of what plans may do. We note that the policy currently housed in §§ 422.2264 and 423.2264, ''Guidelines for CMS Review,'' have been incorporated into the newly proposed §§ 422.2267 and 423.2267. However, whereas the current §§ 422.2264 and 423.2264 provide general guidance on important information that plans must provide to a beneficiary interested in enrolling, §§ 422.2267 and 423.2267 are structured to provide more detailed information on the specific materials or content that a plan is required to produce. Collectively, the required materials and content outlined in §§ 422.2267 and 423.2267 account for the requirements in the current §§ 422.2264 and 423.2264.

We next propose to codify requirements for plan websites at new §§ 422.2265 and 423.2265. The current regulations at §§ 422.111(h)(2) and 423.128(d)(2) establish the requirement for Part C and Part D plans to have an internet website and include requirements regarding content that must be posted on the website. The MCMG has historically provided additional detail on required website content, together with the dates in which the content was required to be posted on a yearly basis. These proposed regulations would redesignate the requirement to have a website at §§ 422.2265 and 423.2265 and supplement that requirement with the additional standards and requirements for websites that are currently in section 70 of the MCMG.

We next propose to codify, in §§ 422.2266 and 423.2266, requirements plans must follow for activities in a healthcare setting, including requirements for provider-initiated activities, plan-initiated provider activities, and plan activities. These requirements are currently articulated in §§ 422.2268(b)(7) and 423.2268(b)(7) and expanded upon in section 60 of the MCMG.

We next propose to codify, at new §§ 422.2267 and 423.2267, instructions for how plans should submit required materials to CMS for review. Specifically, we propose to codify the guidance regarding benchmarks for standardizing and monitoring the production of required documents, including a listing of these required documents, currently found in section 100 and Appendices 2, 3, 4, and 5 of the MCMG. Some of these required materials are discussed in the current regulations (for example, the Annual Notice of Change (ANOC) and the Evidence of Coverage (EOC)). There are some, however, that are only described in the MCMG (for example, the Summary of Benefits (SB)). We propose to codify all of the required materials and content in §§ 422.2267(e) and 423.2267(e); in doing so, we refer to current established regulatory authority when relevant.

Finally, we propose to consolidate, at §§ 422.2274 and 423.2274, requirements related to plan compensation to agents, brokers and other third parties currently found at §§ 422.2272, 422.2274, 423.2272, and 423.2274, and section 110 of the MCMG. For the most part, we do not propose to change the policies currently laid out in these sections but we are proposing significant technical and organizational edits that were

necessary to improve clarity and reduce duplication in the process of consolidation. We refer readers to section V.D. of this proposed rule, where we propose a new policy regarding referral and finder's fees for agents and brokers. Additionally, we are codifying our method for calculating fair market value for agent/broker compensation, as current regulations limit compensation to fair market value but do not further define it or provide the methodology CMS uses for calculating it. CMS first developed the FMV calculation used for purposes of regulating the compensation paid to agents and brokers by plans for contract year 2009 and published these rates in an HPMS memo on December 24, 2008. To develop the FMV, we requested that plans submit the broker fees they paid for 2006 and 2007, as well as the fees planned to be paid in 2009. Plans submitted approximately 19,000 records that we analyzed based on geographic location and organization type. Following this analysis, we developed the FMV for MA plans, 1876 cost plans and Part D plans. The MA FMV rates for enrolling a single beneficiary were established at a national rate of $400, with exceptions for Connecticut, Pennsylvania, and DC ($450), and California and New Jersey ($500), based on higher rates being reported in those geographic areas. The PDP rate was set at $50 for a single enrollment nationally. For years after contract year 2009, we calculated the FMV based on the National Per Capita MA Growth Rate for aged and disabled beneficiaries for Part C and 1876 Cost plans and the Annual Percentage Increase for Part D. The formula is as follows: Current Year FMV + (Current Year FMV * National Per Capita MA Growth Rate for aged and disabled beneficiaries) for MA and 1876 cost plans and Current Year FMV + (Current Year FMV * Annual Percentage Increase for Part D) for PDP plans.

Additionally, section 110.7.1 of the MCMG clarifies when the regulations at §§ 422.2274(b)(2) and 423.2274(b)(2) that require recovery of agent compensation when a newly-enrolled individual disenrolls within the first three months of enrollment (rapid disenrollment) don't apply. We propose to codify those clarifications at §§ 422.2274(g)(2)(ii)(C) and 423.2274(g)(2)(ii)(C).

To reiterate and summarize, the proposed new and revised regulatory sections and their content are as follows:

- Sections 422.2260 and 423.2260 revise and streamline the current definitions of ''communications'' and ''marketing,'' and codify definitions for additional key terms used throughout the proposed regulations from the MCMG.
- Sections 422.2261 and 423.2261 contain requirements for plans to submit certain materials to CMS for review, the process for CMS review and the standards by which CMS will perform the review, taken from current §§ 422.2262, 422.2264, 423.2622, and 423.2264 and section 90 of the MCMG.
- Sections 422.2262 and 423.2262 specify the general standards for plan communications materials and activities, including endorsements and testimonials, and examples of what plans may and may not do. These sections also contain requirements related to standardization of certain key elements of communications materials (specifically, telephone numbers and material IDs). These sections include policies currently articulated in §§ 422.2268 and 423.2268 as well as sections 30 and 90.1 of the MCMG.
- Sections 422.2263 and 423.2263 contain requirements for how plans must conduct marketing. These sections will incorporate requirements currently in §§ 422.2268 and 423.2268 as well as additional guidance from section 40 of the MCMG.
- Sections 422.2264 and 423.2264 address the rules for plan contact with Medicare beneficiaries. These sections include guidance currently in §§ 422.2268 and 423.2268 and further expanded upon in sections 40 and 50 of the MCMG.
- Sections 422.2265 and 423.2265 explain the requirements for plans to have a website as well as what must, can, and must not be on the website. These sections include material currently in section 70 of the MCMG.
- Sections 422.2266 and 423.2266 contain the requirements plans must follow for activities in a healthcare setting. These sections include material from current §§ 422.2268 and 423.2268 and from section 60 of the MCMG.
- Sections 422.2267 and 423.2267 provide instructions on materials and content that CMS requires plans to deliver or make available to beneficiaries, including required disclaimers. These sections include material from section 100 and Appendices 2, 3, 4, and 5 of the MCMG.
- Sections 422.2274 and 423.2274 consolidate requirements from §§ 422.2272, 422.2274, 423.2272, and 423.2274 and section 110 of the MCMG regarding agents, brokers, and compensation to third parties Except as specifically described in the section of the proposed rule, these provisions would codify already-existing guidance and policies and therefore are not expected to have impact.

Finally, we request comment on how CMS should implement prohibitions related to plan marketing during the open enrollment period (OEP). Section 1851(e)(2)(G)(3)(iv) of the Act, as added by section 17005 of the Cures Act, prohibits marketing the opportunity afforded by the open enrollment period (OEP). The current regulations implementing the statutory prohibition on plan marketing during the OEP are at §§ 422.2268(b)(10) and 423.2268(b)(10). The MCMG includes some additional guidance about what activities fall within this prohibition. Specifically, plans are prohibited from sending unsolicited materials that call out the opportunity afforded by the OEP, using mailing lists or other anecdotal information to target individuals who made enrollment requests during the annual coordinated enrollment period (AEP), or leveraging agent/broker activities that target the OEP as a way to make further sales.

I. Past Performance (§§ 422.502 and 423.503)

Since the publication of the first Medicare Advantage (MA) and Part D program regulations in 2005, CMS has established, at §§ 422.502(b) and 423.503(b), that we may deny an application submitted by an organization seeking an MA or Part D sponsor contract if that organization has failed to comply with the requirements of a previous MA or Part D contract. In the April 2011 final rule, we completed rulemaking that placed limits on the period of contract performance CMS would review (that is, 14 months preceding the application deadline) and established that CMS would evaluate contract compliance through a methodology that would be issued periodically through sub-regulatory guidance (75 FR 19684 through 19686). In the April 2018 final rule, we reduced the review period to 12 months (83 FR 16638 through 16639).

In this proposed rule, CMS seeks to add clarity and predictability to our review of MA and Part D applicants' prior MA or Part D contract performance by identifying in the regulation text the criteria we will use to make a determination to deny an application based on prior contract performance. This approach will replace the past performance methodology that CMS developed and issued annually through sub-regulatory guidance.

CMS' overall policy with respect to past performance remains the same. We have an obligation to make certain that MA organizations and Part D sponsors

can fully manage their current contracts and books of business before further expanding. CMS may deny applications based on past contract performance in those instances where the level of previous non-compliance is such that granting additional MA or Part D business opportunities to the responsible organization would pose a high risk to the success and stability of the MA and Part D programs and their enrollees. Accordingly, we propose to adopt three factors, each of which, on its own, represents significant non-compliance with an MA or Part D contract, as bases for denying an MA or Part D application: (A) The imposition of civil money penalties or intermediate sanctions, (B) low Star Ratings scores, and (C) the failure to maintain a fiscally sound operation. We propose that the presence of any one of these factors in an applicant's record during the past performance review period could subject it to the denial of its MA or Part D application. Once finalized, these three bases would be added to our already codified authority and may be used to deny an application based on CMS' termination of an applicant's previous contract under §§ 422.502(b)(3) and 423.503(b)(3). Also, we decline to consider an application from an organization still covered by the 2-year period during which it had agreed, pursuant to §§ 422.508(c) and 423.508(e), not to submit applications for new MA or Part D contracts as part of a mutual termination agreement entered into with CMS pursuant to §§ 422.508(a) and 423.508(a).

In the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2103 and Other Changes Final Rule, CMS established through rulemaking that MA organizations and Part D sponsors are required to achieve Part C or Part D summary ratings scores, respectively, of at least three stars (77 FR 22108 through 22115). In addition, we established that an organization's failure over three consecutive years to achieve Part C or Part D summary ratings of at least three stars is a basis for a CMS-initiated contract termination. In effect, through this rulemaking, CMS established that the failure to achieve at least three stars constitutes a substantial failure to comply with an MA or Part D contract, forming the basis for a CMS-initiated termination. Given the significant impact of low Star Ratings on an organization's ability to continue to hold an MA or Part D contract, we propose to adopt failure to achieve at least a three-star Part C or Part D summary rating in the set of Star Ratings CMS issued during the 12-month review period (CMS currently issues ratings in October of each year) as a basis for denying an application based on past performance. (For example, an application for contract year 2022 would be denied if the organization received less than a three-star rating for contract year 2021, as issued by CMS in October 2020.) In the event that an MA organization requests a review of its eligibility for a Quality Bonus Payment (QBP) under § 422.260, we will use the summary rating that results from the completion of the review process, even if the final decision is not issued until after the expiration of the 12-month review period.

Inherent in a current MA organization or Part D sponsor's submission of a contract qualification application is a representation that it has the financial resources necessary to administer additional lines of Medicare business. A sponsor that CMS has determined does not comply with the financial solvency requirements of § 422.504(b)(14) or § 423.505(b)(23) is not only not in compliance with its current MA or Part D contract, but also would place enrollees of future plans, if it were awarded a new contract, in immediate risk of being unable to gain access to covered benefits should the contracting organization fail to pay legitimately submitted claims. Therefore, CMS believes that an applicant's failure to comply with the solvency requirements also provides a basis, on its own, for the denial of the application based on poor past contract performance.

CMS-imposed intermediate sanctions (for example, suspension of marketing and enrollment activities) and civil money penalties (CMPs) are based on findings of substantial contract compliance failures, consistent with the standards established in sections 1857(g) and 1860D–12 (b)(3)(E) of the Act. For example, the statute (and the corresponding regulations at part 422, subpart O, and part 423, subpart O) provide for the imposition of sanctions or CMPs when a contracting organization substantially fails to provide medically necessary items that are required to be provided to plan enrollees, charges enrollees excess premiums, or contracts with excluded providers. Given the significance of any conduct that would meet these standards, it follows that CMS would consider the imposition of an intermediate sanction or CMP as a failure to comply with an MA or Part D contract warranting the denial of a contract application from that same organization.

In § 422.502(b)(1)(i)(A), we propose to exclude intermediate sanctions imposed on dual eligible special needs plans (D–SNPs) under § 422.752(d) as a basis for denying a MA or Part D application. In the April 2019 final rule, CMS established standards, effective 2021, for the integration of Medicare and Medicaid benefits for D–SNPs pursuant to section 50311(b) of the BBA of 2018, which amends section 1859 of the Act (84 FR 15696 through 15720). We also codified in the April 2019 final rule a requirement at § 422.752(d) that CMS impose an enrollment suspension during plan years 2021 through 2025 when we find that a D–SNP is non-compliant with those integration standards, pursuant to section 50311(b) of the BBA of 2018, which amended section 1859(f) of the Act. As discussed in the April 2019 final rule preamble (84 FR 15719 through 15720), while the new statutory language in section 1859(f)(8)(D)(ii) of the Act permits the Secretary to impose intermediate sanctions for D–SNPs that failed to meet the integration standards, CMS proposed and finalized a requirement that sanctions always be imposed in this case, rather than initiating outright termination. Additionally § 422.752(d) requires that, in cases where CMS imposes such a sanction, the MA organization submit to CMS a corrective action plan.

To achieve compliance with CMS' integration requirements, D–SNPs must work with the states in which they currently operate to negotiate new contractual terms in their state Medicaid agency contracts required under § 422.107. We recognize that states' experience with Medicare and Medicaid integration efforts, and their capacity to facilitate D–SNP compliance with the new integration requirements, varies significantly. While CMS is engaged in capacity building efforts with D–SNPs and states to ensure successful implementation of the D–SNP integration requirements beginning in 2021, the possibility remains that some D–SNPs—despite good faith efforts—may be unsuccessful in meeting their state Medicaid agency contract requirements timely and will therefore be subject to an enrollment sanction under § 422.752(d).

Our proposed policy at § 422.502(b) to deny applications based on past contract performance applies at the MA organization level. However, D–SNP integration requirements apply at the plan level. In most cases, D–SNP PBPs are commingled in contracts that include multiple other non-D–SNP PBPs, such that a sanction imposed on just one D–SNP that is part of an MA

organization with many other plans could result in an inability for the entire MA organization to expand if the proposal were finalized at § 422.502(b)(1)(i)(A), even if that sanctioned D–SNP is working in good faith with a state to meet the relevant integration requirements. Additionally, as noted earlier, § 422.752(d) requires that D–SNPs sanctioned for not meeting the integration criteria submit to CMS a corrective action plan, and CMS retains the ability to terminate a contract or plan for failure to submit such a corrective action plan or to abide by its terms. Therefore, we believe that excluding from the proposed requirement at § 422.502(b)(1)(i)(A) any sanctions CMS imposes on an MA organization with one or more D–SNPs sanctioned specifically under § 422.752(d), during plan years 2021 through 2025, is reasonable given the established mechanism for D–SNPs to be penalized for failure to meet integration requirements established in the April 2019 final rule.

For one of these proposed bases for application denial to be considered, the relevant non-compliance must be documented by CMS (through the issuance of a letter, report, or other publication) during the 12-month review period established at §§ 422.502(b)(1) and 423.503(b)(1). Thus, CMS may include in our analysis conduct that occurred prior to the 12-month past performance review period but either did not come to light, or was not documented, until sometime during the review period.

In evaluating applications submitted by organizations with no recent MA or Part D contracting history, we propose to consider the performance of contracts held by the applicant's parent organization or another organization controlled by the same parent and ascribe that performance to the applicant. Specifically, we propose to identify applying organizations with no recent prior contracting history with CMS (that is, a legal entity brand new to the Medicare program, or one with prior Medicare contract experience that precedes the 12-month review period). We would then determine whether that entity is held by a parent of other MA organizations or Part D sponsors or otherwise shares common control with another contracting organization. In these instances, it is reasonable in the absence of any recent actual contract performance by the applicant due to a lack of recent Part C or Part D participation, to impute to the applicant the performance of its sibling organizations as part of CMS' application evaluation. This approach would prevent parent organizations with subsidiaries that are poor Part C or Part D performers, or the parties that otherwise control poor performing entities, from evading CMS' past performance review authority by creating new legal entities to submit Part C or Part D applications. It would also force organizations responsible for a poor past performance record to direct their attention away from acquiring new Medicare business when their focus should be on bringing their current Medicare contract performance up to an acceptable level. Should one or more of the sibling organizations meet one of the bases for denial stated in (b)(1)(i), the application from the new legal entity would be denied.

We propose to codify the new bases for application denial based on past contract performance as paragraphs (b)(1)(i)(A)—low star ratings, (b)(1)(i)(B)—intermediate sanction or CMP, and (b)(1)(i)(C)—failure to maintain fiscally sound operation under §§ 422.502 and 423.503. The provision governing the consideration of applicant's parent organizations or sibling entities will be stated at §§ 422.502(b)(1)(ii) and 423.503(b)(1)(ii).

J. Prescription Drug Plan Limits (§ 423.265)

Section 1857(e)(1) of the Act, incorporated for Part D by section 1860D–12(b)(3)(D) of the Act, provides CMS with the authority to establish additional contract terms, not inconsistent with Part D, that CMS finds ''necessary and appropriate.'' Section 1860D–11(d)(2)(B) of the Act provides CMS with the authority to negotiate bids and benefits that is ''similar to'' the statutory authority given to the Office of Personnel Management (OPM) in negotiating health benefit plans. We interpreted this authority to mean that we can negotiate a plan's administrative costs, aggregate costs, benefit structure and plan management (70 FR 4296). CMS regulations at §§ 423.272(a) and 423.272(b) require Part D sponsors to submit bids and benefit plans for CMS approval. As stated in § 423.272(b), CMS approves the plan only if the plan's offerings comply with all applicable Part D requirements. Similarly, regulations at § 423.265(b)(2) require that multiple plan offerings by Part D sponsors represent meaningful differences to beneficiaries with respect to beneficiary out-of-pocket costs or formulary structures.

As we have gained experience with the Part D program, we have made consistent efforts to ensure that the number and type of PBPs PDP sponsors may market to beneficiaries are no more numerous than necessary to afford beneficiaries choices from among meaningfully different plan options. CMS has declined to approve more than three stand-alone prescription drug plans offered by a Part D sponsor in a PDP region—one basic plan and (at most) two enhanced plans. A basic plan consists of the following: (1) Standard deductible and cost-sharing amounts (or actuarial equivalents), (2) an initial coverage limit based on a set dollar amount of claims paid on the beneficiary's behalf during the plan year, (3) a coverage gap phase, and (4) a catastrophic coverage phase that applies once a beneficiary's out-of-pocket expenditures for the year have reached a certain threshold. An enhanced plan is an optional plan offering, which provides additional value to beneficiaries in the form of reduced deductibles, reduced cost sharing, additional coverage of some or all drugs while the beneficiary is in the gap phase of the benefit, coverage of drugs that are specifically excluded as Part D drugs under paragraph (2)(ii) of the definition of Part D drug under § 423.100, or some combination of those features. Section 423.104(f)(2) prohibits a Part D sponsor (as defined in § 423.4) from offering enhanced alternative coverage in a service area unless the sponsor also offers a prescription drug plan in that service area that provides basic prescription drug coverage.

Prior to adopting regulations requiring meaningful differences between each plan sponsor's plan offerings in a PDP Region, our guidance allowed sponsors to offer additional basic plans in the same region as long as they were actuarially equivalent to the basic plan structure described in statute. However, under § 423.265(b)(2), PDP sponsors are no longer permitted to offer two basic plans in a PDP Region because Part D sponsors cannot demonstrate a meaningful difference between two basic plans and still satisfy statutory actuarial equivalence requirements. In addition, we believe that allowing more than one basic plan could result in sponsor behaviors that adversely affect the program, such as the creation of plan options designed solely to engage in risk segmentation whereby one basic plan would target enrollment of the LIS beneficiaries and the second basic plan would target a lower risk population. As it stands, healthier beneficiaries are increasingly being incentivized to enroll in low premium enhanced plans, leading to a higher risk pool in the basic plans. Permitting a sponsor to offer two basic plans in a region could ultimately result in increasing bids and premiums

for basic plans, given that LIS auto-enrollment is limited to basic plans. Total government costs would likely increase because CMS pays most of the premium for LIS beneficiaries.

Since the beginning of the Part D program, CMS has consistently tried to ensure that Part D sponsors only market the number and type of PBPs necessary to offer beneficiaries meaningfully different plan options and allow them to carefully examine all of the plan offerings. However, allowing sponsors to offer enhanced prescription drug plan offerings that are not meaningfully different with respect to beneficiary out-of-pocket costs can lead to more innovation and provide sponsors with added flexibility to offer health care options that can be tailored to different beneficiary choices with a portfolio of plan options with different benefits, pharmacy networks, and premiums. As such CMS eliminated the meaningful difference requirement between a plan sponsor's enhanced alternative benefit offerings effective for contract year 2019. As a result of eliminating this requirement, we have seen a greater number of enhanced plan offerings.

CMS has examined Part D plan payment data in cases and markets with different numbers of enhanced plans. When looking at this data, we noted that markets with a greater number of enhanced plans have higher costs than basic plans. This was true even when controlling for other factors, such as population health and age. In these cases, the basic component of enhanced plans' bids was found to trend higher than basic plan bids themselves. Given the upward impact to program costs, CMS proposes to codify our policy of limiting number of allowed enhanced plan offerings by a Part D sponsor in a PDP region.

We believe that limiting a Part D sponsor to three plan offerings per region, (that is, one basic and, at most, two enhanced plans), strikes the right balance between encouraging robust competition and flexibility for plan sponsors to innovate with the need to limit the potential for significant risk segmentation and provide beneficiaries with only clear options that do not create confusion and allow for careful examination of the available choices. Based on our review of current and past plan offerings and our actuarial models, we believe that permitting more than 3 plan options likely would lead to more enhanced plans that offer only the minimum level of supplemental coverage required to meet our meaningful differences tests. These ''low value enhanced plans'' sometimes have lower premiums than basic plans because of the risk profile of the enrollees, as low income subsidy (LIS) enrollees with more serious health issues and higher utilization of prescription drugs generally are not enrolled in these plans because they would be responsible for paying the supplemental premium out of pocket (even though the total premium is less than the basic plan). When many healthy individuals are not included in the basic plans, the cost of the basic plans is increased, and this in turn increases low-income premium subsidies.

We do not believe such risk segmentation is consistent with the design of the Part D program, which has been put in place to save taxpayers' and Medicare beneficiaries' money on prescription drug costs. We do not believe such risk segmentation obtains the best value for the government or the taxpayer. We believe sponsors compete in the Part D market by offering their best bids for basic plans, in order to attract the greatest enrollment through the lowest premiums, and that this competition maintains downward pressure on Part D bids and government subsidies. Our proposal to codify a 3 plan limit would not eliminate the potential for some risk segmentation, but would limit risk segmentation and would prevent any potential growth in plan offerings that could further segment risk.

We are proposing to limit Part D sponsors to offering no more than three prescription drug plans per PDP region by adding a new paragraph at § 423.265(b)(2). Since this proposed change would codify our existing practice, this proposed change would not alter any existing processes or procedures within the Part D bid submission and approval process. Therefore, this provision is not expected to have a budgetary impact.

We seek stakeholder input as to the impact of limiting the number of enhanced plan offerings to two. In addition, we are seeking information on what type of impact expanding the number of enhanced plan alternatives would have and whether there is any real need for more than two standalone enhanced plan options per PDP sponsor per PDP region.

K. Definition of a Parent Organization (§§ 422.2 and 423.4)

Pursuant to our authority under sections 1856(b) and 1860D–12(f)(1) of the Act, we propose to codify our definition of parent organization for purposes of the MA and Part D programs as the legal entity exercising controlling interest in an MA organization or Part D sponsor. We propose adding a definition for the term ''parent organization'' to § 422.2 in part 422, subpart A, and § 423.4 in part 423, subpart A, to reflect this understanding.

This proposal is to ensure that the MA and Part D programs apply a consistent definition of parent organization. CMS uses the identity of an MA organization's or Part D sponsor's parent organization in a variety of operational contexts, including, but not limited to:

—Determining whether an individual can be deemed to have elected an MA dual eligible special needs plan based in part on his enrollment in an affiliated Medicaid managed care plan (§ 422.66(c)(2));

—Accounting for contract consolidations in assigning Star Ratings under the Quality Rating System for health and/or drug services of the same plan type under the same parent organization (§§ 422.162 and 423.182);

—Determining whether a new MA contract constitutes a new MA plan for calculation of star ratings, benchmarks, quality bonus payments, and beneficiary rebates, (§ 422.252).

—Recognizing an individual's appointment as an MA organization's or Part D sponsor's compliance officer based on his or her status as an employee of the organization, its parent organization, or a corporate affiliate (§§ 422.503(b)(4)(vi)(B)(*1*) and 423.504(b)(4)(vi)(B)(*1*));

—Determining whether an applicant for a new PDP contract is eligible to receive a contract in a particular service area (§ 423.503(a)(3)) after evaluating whether the approval of an application would result in a parent organization, directly or through its subsidiaries, holding more than one PDP contract in a PDP region;

—Determining whether to administer an essential operations test to a Part D contract applicant new to the Part D program (§§ 423.503(c)(4) and 423.505(b)(27)), taking into account the exemption for subsidiaries of parent organizations that have existing Part D business from the essential operations test;

—Releasing summary Part D reconciliation payment data at the parent organization level (§ 423.505(o)); and

—Determining whether CMS will recognize the sale or transfer of an organization's PDP line of business, where CMS regulations require the transfer of all PDP contracts held by the selling or transferring sponsor unless the sale or transfer is between wholly owned subsidiaries of the

same parent organization (§ 423.551(g)).

We currently define the term ''parent organization'' for purposes of applying the prohibition against approving an application that would result in a parent organization holding more than one PDP sponsor contract in a region as an entity that exercises a controlling interest in the sponsor. (See § 423.503(a)(3)). Because we are proposing a more detailed definition that would apply throughout the MA and Part D programs, we are proposing to delete that language in § 423.503(a)(3).

Under the proposed definition, a parent organization is the legal entity that holds a controlling interest in the MA organization or Part D sponsor, whether it holds that interest directly or through other subsidiaries. The controlling interest can be represented by share ownership, the power to appoint voting board members, or other means. Control of the appointment of board members is particularly relevant with respect to not-for-profit organizations, where there is often no direct corollary to the ownership of corporate shares in for-profit organizations. We recognize that the many ways that one legal entity may have a controlling interest in another legal entity are varied and could take many forms too numerous for us to create an exhaustive list. Therefore, our proposal includes the ability for us to look at other means of control to be exercised or established. We invite comment on other examples of the form a controlling interest might take.

We further propose to specify that the parent organization cannot itself be a subsidiary of another entity. This ensures that each MA organization or Part D sponsor has a single parent organization for purposes of the MA and Part D programs. For example, if Company A owns 80 percent of Company B, which in turn owns 100 percent of an MA organization, Company A would be the parent organization of the MA organization under the proposed definition.

We believe that the proposed definition will codify current policy and ensure continued consistency throughout the MA and Part D programs. We note that this definition of parent organization would apply in implementing the proposed change to § 422.550 regarding the type of change of ownership that CMS would permit for MA contracts; we discuss that proposal in section VI.D. of this proposed rule.

L. Call Center Requirements (§§ 422.111 and 423.128)

In implementing sections 1851(d) and 1860D–4(a)(3) of the Act, CMS established, at §§ 422.111(h) and 423.128(d), that MA organizations and Part D sponsors are required to have in place a mechanism for providing, on a timely basis, specific information to current and prospective enrollees, and for a Part D plan also to pharmacies in the plan network, upon request. One of these enumerated mechanisms includes operating a toll-free customer service call center. In this proposed rule, CMS seeks to add greater specificity and clarity to our requirements for MA and Part D plans by delineating more explicit performance standards for MA and Part D customer service call centers, as well as ensuring greater protections for beneficiaries. This approach will enhance the current approach, providing plans clear standards under which to operate their customer service call centers and eliminating uncertainty with regard to CMS's expectations. Customer service call centers include call centers operated for current enrollees, prospective enrollees, and for pharmacies in plans' networks that are seeking information on drug coverage for customers enrolled in a particular plan. For the most part, this proposal would codify existing guidance. Under our proposal, CMS's overall policy with respect to operating a toll-free customer service call center would remain largely the same. We have always expected MA organizations and Part D sponsors to operate customer service call centers in a way that ensures beneficiaries and pharmacies have timely and accurate access to information about benefits in a manner that they can understand and use. Providing specific performance standards in regulation text will clearly lay out the performance requirements and our expectations for customer service call centers. Additionally, beneficiaries will benefit from CMS holding plans to clearly defined call center standards. Accordingly, we propose to adopt the following performance requirements for call center functionality. Failure to comply with any of these requirements would represent significant deviation from acceptable call center operational practices and a significant risk to beneficiaries' well-being under our enforcement policies and applicable regulations.

In §§ 422.111(h)(1)(i) and 423.128(d)(1)(i), we propose that customer service call centers must be open from at least 8:00 a.m. to 8:00 p.m., local time, in all service areas and regions served by the MA or Part D plan, and for Part D plans, that any call center serving network pharmacies or pharmacists employed by those pharmacies must be open any time a pharmacy in the plan service area is open. We remind stakeholders that MA–PD plans are Part D plans that must comply with Part 423 requirements. These proposed timeframe standards lend greater specificity to the previous iteration of this regulation which only required a call center to be open during ''normal business hours.'' We believe that 8:00 a.m.–8:00 p.m. constitutes normal business hours for beneficiary access, based both on our knowledge of industry-wide practices and our experience with MA and Part D plans' call center operations in particular. The requirement for call centers serving network pharmacies to be open any time a pharmacy in that network in the plan's service area is open reflects the need to resolve questions about benefits and coverage promptly at the point of sale. The vast majority of current MA and Part D plans meet these standards. By requiring plans to be open from 8:00 a.m. to 8:00 p.m. in all service areas or regions served by that Part C or D plan, CMS is ensuring that in instances in which plans operate in service areas that straddle multiple time zones, all beneficiaries and pharmacists have equal access to call center services.

We are proposing in §§ 422.111(h)(1)(ii) and 423.128(d)(1)(ii) a series of minimum requirements that define specific operational requirements for customer service call centers. In paragraph (h)(1)(ii)(A), CMS proposes to codify the requirement that the average hold time be two minutes or less. We are proposing specific text to explain when the two minute count starts to ensure consistent application of the metric by defining the hold time as the time spent on hold by callers following the interactive voice response (IVR) system, touch-tone response system, or recorded greeting, before reaching a live person. In paragraph (h)(1)(ii)(B), CMS proposes to codify the requirements that the call center answer 80 percent of incoming calls within 30 seconds after the Interactive Voice Response (IVR), touch-tone response system, or recorded greeting interaction. In paragraph (h)(1)(ii)(C), CMS proposes to codify the requirement that 5 percent or less of incoming call calls be disconnected or unexpectedly dropped by the plan customer call center. These standards both ensure that beneficiaries can consistently access call centers in a timely manner and set thresholds that plans can reasonably attain. Data

gathered from our call center monitoring studies indicates that 90 percent of MA organizations and Part D sponsors have average hold times of less than two minutes, 87 percent answer 80 percent incoming calls within 30 seconds, and 82 percent have disconnect rates of less than 5 percent. Longstanding CMS policy interpreting the current regulatory requirement for the call center to meet standard business practices requires call centers to answer calls within 30 seconds and plans overwhelmingly comply with this requirement.

CMS also proposes to amend §§ 422.111(h)(1)(iii) and 423.128(d)(1)(iii) to further delineate accessibility requirements for non-English speaking and limited English proficient (LEP) individuals. Plans have always been required to provide interpreters as that is consistent with existing civil rights laws. We propose to further require that interpreters be available within 8 minutes of reaching the customer service representative and that the interpreter be available at no cost to the caller. These requirements are consistent with our interpretation of the requirement for call centers to meet standard business practices and performance is measured against this standard in our current monitoring and oversight activities. Data from our call center monitoring indicates that 95% of plans already meet this standard.

CMS proposes to add §§ 422.111(h)(1)(iv) and 423.128(d)(1)(v), explicitly requiring that call centers respond to TTY-to-TTY calls, consistent with standards established under existing law governing access for individuals with disabilities at 47 CFR part 604, subpart F. The Rehabilitation Act and the Americans with Disabilities Act already require the provision of accessibility services for individuals with disabilities, such as deaf or hard-of-hearing individuals. We are also proposing, at §§ 422.111(h)(1)(v) and 423.128(d)(1)(v), that when using automated-attendant systems, MA and Part D plans must provide effective real-time communication with individuals using auxiliary aids and services, including TTYs and all forms of FCC-approved telecommunications relay systems. See 28 CFR 35.161, 36.303(d). The requirements proposed at §§ 422.111(h)(1)(ii) and 423.128(d)(1)(ii) also apply to TTY-to-TTY calls. CMS will hold plans accountable for complying with the requirements of §§ 422.111(h)(1)(ii) and 423.128(d)(1)(ii) when receiving TTY-to-TTY calls. These standards are consistent with current CMS interpretation and implementation of the requirement that plans have a call center that meets standard business practices. CMS data shows that 91 percent of plans currently respond to TTY-to-TTY calls within 7 minutes. CMS solicits comments on adopting the 7 minute response time as a TTY-to-TTY standard.

We propose to codify our existing interpretations and policies regarding MA and Part D plan call centers as explicit requirements for operating a toll-free customer service call center in §§ 422.111 and 423.128. We are proposing this codification to ensure transparency for plans about the performance standards they must meet. Further, codification of these policies will provide stability for these plans going forward.

M. Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38)

1. Part C Special Election Periods (§ 422.62)

Section 1851(e)(4) of the Act establishes special election periods (SEPs) during which, if certain circumstances exist, an individual may request enrollment in a Medicare Advantage (MA) plan or discontinue the election of an MA plan and change his or her election to original Medicare or to a different MA plan. We have codified SEPs for the following circumstances specifically addressed in section 1851(e)(4) of the Act:

- When CMS terminates the MA organization's contract for the plan, or the MA organization terminates the plan or discontinues offering the plan in the service or continuation area in which the individual resides, or the MA organization has notified the individual of the impending termination of the plan or the impending discontinuation of the plan in the area in which the individual resides (§ 422.62(b)(1) and section 1851(e)(4)(A) of the Act).
- When the individual is no longer eligible to be enrolled in a certain plan due to a change of residence or other change in circumstances as specified by CMS but not including terminations resulting from a failure to make timely payment of an MA monthly or supplemental beneficiary premium, or from disruptive behavior (§ 422.62(b)(2) and section 1851(e)(4)(B) of the Act).
- When the individual demonstrates to CMS, in accordance with guidelines established by CMS that the MA organization has substantially violated a material provision of its contract or materially misrepresented the plan's provisions in marketing the plan in relation to the individual (§ 422.62(b)(3) and section 1851(e)(4)(C) of the Act).

Section 1851(e)(4)(D) of the Act also grants the Secretary the authority to create SEPs for individuals who meet other exceptional conditions. This authority is codified at § 422.62(b)(4). CMS has historically included in regulation those SEPs that the statute explicitly authorizes and has established the SEPs for exceptional circumstances in our subregulatory guidance rather than through regulation. We are now proposing to codify a number of SEPs that we have adopted and implemented through subregulatory guidance as exceptional circumstances SEPs. Except where noted in this proposed rule, our intent is to codify the current policy, as reflected in section 30.4.4 of Chapter 2 of the Medicare Managed Care Manual. As with all MA enrollments, enrollments into a new MA plan using a SEP require that the individual be otherwise eligible for that MA plan under §§ 422.50 through 422.57. For example, the individual must reside in the service area of the new MA plan. We seek specific comment as to whether we have overlooked any feature of the current policy that should be codified and if there are other exceptional circumstances we have not identified for which we should consider establishing a special election period. Codifying our current policy for these SEPs will provide transparency and stability for stakeholders about the MA program and about the nature and scope of these SEPs by ensuring that the SEPs are changed only through additional rulemaking. Consistent with § 422.68(c), we are also proposing to revise § 422.68(d) to clarify that for SEPs that are described in § 422.62(b), elections are effective as of the first day of the first calendar month following the month in which the election is made, unless otherwise noted. In addition, we note that, consistent with longstanding subregulatory guidance, the organization is not required to contact an applicant to confirm SEP eligibility if the enrollment request includes the applicant's attestation of SEP eligibility.

- *SEP for Employer/Union Group Health Plan (EGHP) Elections.* We are proposing to revise § 422.62(b)(4) to codify a SEP for individuals making MA enrollment requests into or out of employer sponsored MA plans, for individuals to disenroll from an MA plan to take employer sponsored coverage of any kind, and for individuals disenrolling from employer sponsored coverage (including COBRA coverage) to elect an MA plan.

This SEP is available to individuals who have (or are enrolling in) an employer or union sponsored plan for the duration of that enrollment and ends 2 months after the month the employer or union coverage ends. The individual may choose an effective date of up to three months after the month in which the individual completed an enrollment or disenrollment request; however, the effective date may not be earlier than the first of the month following the month in which the request was made.

• *SEP for Individuals Who Disenroll in Connection With a CMS Sanction.* At new § 422.62(b)(5), we are proposing to codify the SEP for individuals enrolled in an MA plan offered by an MA organization that is sanctioned by CMS. Such enrollees would be eligible for a SEP to elect another MA plan, or disenroll to original Medicare and enroll in a PDP, if they believe they are affected by the matter(s) that gave rise to that sanction. We propose that, consistent with § 422.111(g), CMS may require the MA organization to notify the current enrollees that if they believe they are affected by the matter(s) that gave rise to the sanction, they are able to choose another MA plan or enroll in original Medicare and a PDP. The SEP would start with the imposition of the sanction and end when the sanction ends or when the individual makes an election, whichever occurs first.

• *SEP for Individuals Enrolled in Cost Plans That Are Non-Renewing Their Contracts.* At new § 422.62(b)(6), we are proposing to codify the SEP for individuals enrolled in cost plans that are non-renewing their contracts for the area in which the enrollee lives. Such individuals would be eligible for a SEP to elect an MA plan. This SEP would be available only to Medicare beneficiaries who are enrolled with an HMO or CMP under a section 1876 cost plan that will no longer be offered in the area in which the beneficiary lives.

This SEP would begin December 8 of the current contract year, which is the day after the end of the Annual coordinated election period, and end on the last day of February of the following year. Therefore, applying the general rule we propose to codify that elections are effective the first of the month after they are made, enrollment requests received before December 31 would have an effective date of January 1, enrollment requests received between January 1 and January 31 would be effective February 1, and enrollment requests received between February 1 and February 28 (or 29, as the case may be) would be effective March 1.

• *SEP for Individuals in the Program of All-Inclusive Care for the Elderly (PACE).* At new § 422.62(b)(7), we are proposing to codify the SEP allowing an MA plan enrollee to disenroll from an MA plan at any time in order to enroll in PACE. The MA plan enrollee who disenrolls from an MA plan would have a SEP for 2 months after the effective date of MA plan disenrollment to elect a PACE plan. In addition, a PACE enrollee who disenrolls from PACE would have an SEP for 2 months after the effective date of PACE disenrollment to elect an MA plan.

• *SEP for Individuals Who Terminated a Medigap Policy When They Enrolled For the First Time in an MA Plan and Who Are Still in a Trial Period.* For Medicare beneficiaries who terminated a Medigap policy when they enrolled for the first time in an MA plan, section 1882(s)(3)(B)(v) of the Act provides a guaranteed right to purchase another Medigap policy if they disenroll from the MA plan while they are still in a trial period. In most cases, a trial period lasts for 12 months after a person enrolls in an MA plan for the first time. The right to guaranteed issue of a Medigap policy under section 1882(s)(3)(B)(v) of the Act would be meaningless if individuals covered by this provision could not disenroll from the MA plan while they were still in a trial period.

Accordingly, we are proposing, at new § 422.62(b)(8), to codify the SEP for individuals who are eligible for guaranteed issue of a Medigap policy under section 1882(s)(3)(B)(v) of the Act upon disenrollment from the MA plan in which they are enrolled. This SEP would allow a qualified individual to make a one-time election to disenroll from their first MA plan to join original Medicare at any time of the year. The SEP would begin upon enrollment in the MA plan and would end after 12 months of enrollment or when the beneficiary disenrolls, whichever is earlier.

• *SEP for Individuals With ESRD Whose Medicare Entitlement Determination Was Made Retroactively.* If a Medicare entitlement determination based on ESRD is made retroactively, an individual has not been provided the opportunity to elect an MA plan during his or her ICEP. Therefore, we are proposing to codify at new § 422.62(b)(9) that these individuals would have a SEP to prospectively elect an MA plan offered by the MA organization, provided:

++ They were enrolled in a health plan offered by the same MA organization the month before their entitlement to Parts A and B;

++ They developed ESRD while a member of that health plan; and

++ They are still enrolled in that health plan.

This SEP could also be used in cases when there is an administrative delay and the entitlement determination is not made timely. For example, an individual who performs self-dialysis would have his or her entitlement date adjusted to begin at the time of dialysis, rather than the customary 3-month period after dialysis begins.

This SEP would begin the month the individual receives the notice of the Medicare entitlement determination and would continue for 2 months after the month the notice is received. This SEP would be necessary only through the 2020 plan year, as section 17006 of the Cures Act amended section 1851 of the Act to remove the prohibition for beneficiaries with ESRD from enrolling in an MA plan. Although this statutory change is not discussed in current sub-regulatory guidance, we have included this in proposed new § 422.62(b)(9) for clarity.

• *SEP for Individuals Whose Medicare Entitlement Determination Was Made Retroactively.* If a Medicare entitlement determination is made retroactively, an individual has not been provided the opportunity to elect an MA plan during his or her ICEP. Therefore, we are proposing, at new § 422.62(b)(10), to codify the SEP for these individuals to elect an MA plan. This SEP could also be used in cases when there is an administrative delay and the entitlement determination is not made timely by SSA or received by the individual in a timely manner.

The SEP would begin the month the individual receives the notice of the Medicare entitlement determination and would continue for 2 months after the month the notice is received. Consistent with our general rule regarding the effective dates for elections made during an SEP, the election made using this SEP would be effective on the first of the month following the MA organization's receipt of the election but no earlier than the first day of the month in which the notice of entitlement is received. A beneficiary would receive coverage under original Medicare from the date of entitlement until the MA enrollment is effective.

• *SEP for Individuals Who Lose Special Needs Status.* At new § 422.62(b)(11), we are proposing to codify the SEP for individuals enrolled in an MA special needs plan (SNP) who are no longer eligible for the SNP because they no longer meet the applicable special needs status. This SEP would begin the month the individual's special needs status

changes. The SEP would end when the beneficiary makes an enrollment request or the end of the third month after the month of the effective date of involuntary disenrollment from the SNP, whichever is earlier.

• *SEP for Individuals Who Belong to a Qualified SPAP or Who Lose SPAP Eligibility.* At new § 422.62(b)(12), we are proposing to codify a SEP for individuals who belong to a qualified State Pharmaceutical Assistance Program (SPAP) to make one election to enroll in an MA–PD plan each calendar year. SPAP members may use this SEP to enroll in an MA–PD plan outside of existing enrollment opportunities, allowing them, for example, to join an MA–PD plan upon becoming a member of an SPAP. Because SPAP eligibility may influence an individual's choice of MA–PD plan, we have adopted a SEP for MA enrollment to coordinate with the change in SPAP eligibility.

In addition to being available while the individual belongs to the SPAP, the SEP remains available for individuals no longer eligible for SPAP benefits for 2 months. The SEP continues until the month they lose SPAP eligibility or the month they are notified of the loss of SPAP eligibility, whichever is later, and then for an additional 2 months.

• *SEP for Enrollment Into a Chronic Care SNP and for Individuals Found Ineligible for a Chronic Care SNP.* At new § 422.62(b)(13), we are proposing to codify the SEP allowing individuals with severe or disabling chronic conditions to enroll in a Chronic Care SNP (C–SNP) designed to serve individuals with those conditions. This SEP would be available as long as the individual has the qualifying condition and would end once he or she enrolls in a C–SNP. Once the SEP ends, that individual would be able to make enrollment changes only during applicable election periods. In addition, individuals enrolled in a C–SNP who have a severe or disabling chronic condition that is not a focus of their current C–SNP would be eligible for this SEP to change to a C–SNP that does focus on the condition that the individual has. Eligibility for this SEP would end at the time the individual enrolls in the new C–SNP.

Individuals who are found after enrollment not to have the qualifying condition necessary to enroll in a C–SNP would have a SEP to enroll in a different MA plan. This would normally occur when the required post enrollment verification with a provider did not confirm the information provided on the pre-enrollment assessment tool. This SEP would begin when the plan notifies the individual of the lack of eligibility and would extend through the end of that month, plus 2 additional months. The SEP would end when the individual makes an enrollment election or on the last day of the second month following notification.

• *SEP for Disenrollment From Part D To Enroll in or Maintain Other Creditable Coverage.* At new § 422.62(b)(14), we are proposing to codify the SEP that provides an opportunity for individuals to disenroll from an MA–PD plan (only by electing Original Medicare or an MA-only plan) in order to enroll in or maintain other creditable drug coverage (such as TriCare or VA coverage) as defined in § 423.56(b). This SEP may not be used to disenroll from an MA–PD plan by electing another MA–PD plan.

• *SEP to Enroll in an MA Plan With a Star Rating of 5 Stars.* At new § 422.62(b)(15), we are proposing to codify the SEP allowing an eligible individual to enroll in an MA plan with a Star Rating of 5 stars during the plan contract year in which that plan has the 5-star overall rating. A rating of 5 stars is considered ''excellent'' and is the highest performance rating that a plan can achieve. Because these plans have demonstrated exceptional performance, and because there tends to be only a small number of 5 Star plans in a given contract year, we believe a SEP is warranted to allow beneficiaries with access to these plans the opportunity to enroll during the plan year for which the 5 Star rating is applicable. The SEP is available beginning the first day after the Annual Election Period (AEP), December 8, prior to the plan contract year for which the 5 Star Rating is applicable, through November 30 of the plan contract year the 5 Star Rating is applicable. The enrollment effective date would be the first of the month following the month in which the MA organization receives the enrollment request.

An individual using this SEP would be able to enroll in an MA plan with a 5-star overall rating even if coming from original Medicare (with or without concurrent enrollment in a standalone Medicare prescription drug plan). Individuals enrolled in a plan with a 5-star overall rating may also switch to a different plan with a 5-star overall rating. Consistent with our general rules for how enrollment eligibility and elections for Part D and MA work, an individual in a MA-only or MA–PD coordinated care plan who switches to a PDP with a 5-star overall rating would lose MA coverage and will revert to original Medicare for basic medical coverage.

• *SEP for Non-U.S. Citizens Who Become Lawfully Present.* At new § 422.62(b)(16), we are proposing to codify the SEP for non-U.S. citizens who become lawfully present in the United States. The individual would be able to use this SEP to request enrollment in any MA plan for which he or she is eligible. This SEP would begin the month the lawful presence starts and would end when the individual makes an enrollment election or at the end of the second calendar month after the month it begins, whichever occurs first.

• *SEP for Providing Individuals Who Requested Materials in Accessible Formats Equal Time To Make Enrollment Decisions.* As outlined in section 504 of the Rehabilitation Act of 1973, organizations are required to comply with requirements of that Act and provide materials in accessible formats to members. This generally includes formats such as Braille, data, and audio files, or other formats accepted by the member in place of, or in addition to, the original print material.

We are proposing to codify, at new § 422.62(b)(17), the SEP in situations where the MA organization or CMS was unable to provide required notices or information in an accessible format, as requested by an individual, within the same timeframe that it was able to provide the same information to individuals who did not request an accessible format. This limited SEP would ensure that beneficiaries who have requested information in accessible formats are not disadvantaged by any additional time necessary to fulfill their request, including missing an election period deadline.

The SEP would begin at the end of the election period during which the beneficiary was seeking to make an election. The start of the SEP, as well as the enrollment effective date, would be dependent upon the situation, and the length is at least as long as the time it took for the information to be provided to the individual in an accessible format. An individual would be eligible for this SEP when the conditions described in this section are met. MA organizations would be required to maintain adequate documentation of the situation, including records indicating the date of the individual's request, the amount of time taken to provide accessible versions of the requested materials and the amount of time it takes for the same information to be provided to an individual who does not request an accessible format.

• *SEP for Individuals Affected by a FEMA-Declared Weather-Related*

Emergency or Major Disaster. We are proposing to codify, at new § 422.62(b)(18), the SEP for individuals affected by a weather-related emergency or major disaster who were unable to make an election during another valid election period. This would include both enrollment and disenrollment elections. Individuals would be eligible for this SEP if they:

++ Reside, or resided at the start of the incident period, in an area for which Federal Emergency Management Agency (FEMA) has declared an emergency or a major disaster and has designated affected counties as being eligible to apply for individual or public level assistance;

++ Had another valid election period during the incident period; and

++ Did not make an election during that other valid election period due to the emergency or disaster.

In addition, the SEP would be available to those individuals who do not live in the affected areas but rely on help making healthcare decisions from friends or family members who live in the affected areas. The SEP would be available from the start of the incident period and for 4 months after the start of the incident period.

• *SEP for Significant Change in Provider Network.* At new § 422.62(b)(23), we are proposing to codify the SEP that is available when CMS determines that mid-year changes to an MA plan's provider network are significant, based on the effect on, or potential to affect, current plan enrollees' continued access to covered benefits. Mid-year changes are those that are effective other than on January 1. We note that pursuant to § 422.111, an MA plan must furnish information to enrollees before the annual election period about changes in the plan, including changes in the network, that are effective for the next plan year. Because this notice and the annual election period give enrollees the opportunity to change plans for the new year, we have historically limited this SEP to mid-year changes in the network.

CMS considers significant changes to provider networks to be those that go beyond individual or limited provider terminations that occur during the routine course of plan operations and affect, or have the potential to affect, a large number of the MAO's enrollees. CMS will use a variety of criteria for determining whether or not the network terminations are substantial, such as: (1) The number of enrollees affected; (2) the size of the service area affected; (3) the timing of the termination; (4) whether adequate and timely notice is provided to enrollees, (5) and any other information that may be relevant to the particular circumstance(s).

The SEP would be in effect once CMS makes its determination and enrollees have been notified. As with current guidance, we are proposing that the SEP begins the month the individual is notified of the network change and would continue for an additional 2 calendar months after the month in which the enrollee is notified of the SEP. We are proposing for the SEP to begin the month the individual is notified of eligibility for the SEP, as the MA organization may notify members of the network change prior to CMS making its determination, which under current guidance would result in a SEP start date that precedes the existence of the SEP. The SEP would continue for an additional 2 calendar months after the month in which the enrollee is notified of the SEP. Enrollment in the new plan would be effective the first day of the month after the plan receives the enrollment request. This SEP can be used only once per significant change in the provider network.

The scope of individuals eligible for the SEP would be determined by CMS, applying the standards in the regulation, and would include enrollees who have been affected, or who may be affected, by the network change. We propose to define an ''affected enrollee'' as an enrollee who is assigned to, currently receiving care from, or has received care within the past 3 months from a provider or facility being terminated. Individuals eligible for the SEP would be able to disenroll from the MA plan and elect original Medicare or another MA plan, including an MA–PD plan, even if they did not have prescription drug coverage previously. CMS will provide specific instructions directly to the MA organization with the significant network change, including instructions on required beneficiary notifications and information to be provided to affected beneficiaries regarding other enrollment options, if applicable.

• *SEP for Individuals Enrolled in a Plan Placed in Receivership.* We propose to establish a new SEP, at new § 422.62(b)(24), for individuals enrolled in plans offered by MA organizations experiencing financial difficulties to such an extent that a state or territorial regulatory authority has placed the organization in receivership. We believe this SEP constitutes an exceptional circumstance because receiverships have the potential to cause disruption in access to healthcare services and individuals should have the ability to take action to prevent any future disruption to care. The SEP would allow an individual to discontinue the election of an MA plan and change his or her election to a different MA plan or to original Medicare, with or without enrollment in a standalone Medicare prescription drug plan. We propose that the SEP begin the month the receivership is effective and continue until the enrollee makes an election or the receivership is no longer in effect, whichever occurs first.

Also, we propose that when instructed by CMS, the MA plan that has been placed under receivership, or the entity operating the organization in receivership, must notify its enrollees, in the form and manner directed by CMS, of their eligibility for this SEP and how to use the SEP.

• *SEP for Individuals Enrolled in a Plan That Has Been Identified by CMS as a Consistent Poor Performer.* We propose to establish a new SEP, at new § 422.62(b)(25), for individuals who are enrolled in plans identified with the low performing icon (LPI) in accordance with § 422.166(h)(1)(ii). The LPI is assigned to contracts that have summary ratings of less than 3 Stars for three or more years. We believe this SEP constitutes an exceptional circumstance because these contracts have demonstrated performance considered ''below average'' or ''poor'' for a sustained period of time based on critical factors such as beneficiary complaints and access to care. To ensure that beneficiaries are not adversely affected, we believe that beneficiaries enrolled in these contracts should have the ability to enroll in plans rated ''average'' or higher during the year. The SEP would allow an individual to discontinue the election of a consistently poor performing MA plan and change his or her election to an MA plan with an overall Star Rating of 3 or more stars or to original Medicare, with or without enrollment in a standalone Medicare prescription drug plan. We propose that the SEP exist while the individual is enrolled in the consistently poor performing MA plan.

• *SEP for Individuals Affected by a Federal Employee Error.* At new § 422.62(b)(21), we are proposing to codify a SEP for individuals whose enrollment or non-enrollment in an MA–PD plan is erroneous due to an action, inaction or error by a federal employee to permit enrollment in, or disenrollment from, an MA–PD plan. Requests for this SEP would have to be developed and presented to the MA organization's CMS account manager. The CMS account manager will review each case and determine if the enrollment or non-enrollment was caused by the action, inaction or error on the part of a federal employee. This

SEP would begin the month that CMS determines an individual eligible for this SEP and would continue for 2 months.

• *SEP for Other Exceptional Circumstances.* Lastly, we propose to retain the authority currently at § 422.62(b)(4) to create SEPs for individuals who meet other exceptional conditions established by CMS and move it to new § 422.62(b)(26). SEPs established under this authority would be done on a case-by-case basis and in situations which we determine it is in the best interest of the beneficiary to have an enrollment (or disenrollment) opportunity. While our experience with the MA program has informed the SEPs that we have established to date, and are proposing to codify in this regulation, we are mindful that *exceptional circumstances* may arise which may also warrant a SEP, and we note that this list is not meant to be exhaustive.

Also based on the Secretary's authority to create SEPs for individuals who meet exceptional conditions, we propose to codify the following SEPs currently outlined in subregulatory guidance that coordinate with Part D election periods:

• *SEP for Individuals Who Experience an Involuntary Loss of Creditable Prescription Drug Coverage.* At new § 422.62(b)(19), we are proposing to codify the SEP for individuals who experience an involuntary loss of creditable prescription drug coverage, including a reduction in the level of coverage so that it is no longer creditable but not including any such loss or reduction due to a failure to pay premiums, to enroll in an MA–PD plan. The SEP would begin the month in which the individual is advised of the loss of creditable coverage and would end 2 months after either the loss (or reduction) occurs or the individual received notice, whichever is later. The effective date of this SEP may be the first of the month after the request or, at the beneficiary's request, may be up to 3 months prospective.

• *SEP for Individuals Who Are Not Adequately Informed of a Loss of Creditable Prescription Drug Coverage.* At new § 422.62(b)(20), we are proposing to codify a SEP for individuals who are not adequately informed of a loss of creditable prescription drug coverage, or that they never had creditable coverage, to permit one enrollment in, or disenrollment from, an MA–PD plan, on a case-by-case basis. CMS will review each case and determine whether an entity offering prescription drug coverage failed to provide accurate and timely disclosure of the loss of creditable prescription drug coverage or whether the prescription drug coverage offered is creditable. This SEP would begin the month that CMS determines an individual eligible for this SEP and would continue for 2 months.

• *SEP for Individuals Eligible for an Additional Part D IEP.* At new § 422.62(b)(22), we are proposing to codify the SEP for an individual who is eligible for an additional Part D Initial Enrollment Period (IEP) to have an MA SEP to coordinate with the additional Part D IEP. One example of a Part D IEP is the one for an individual currently entitled to Medicare due to a disability and who is attaining age 65. The IEP for Part D permits enrollment in a Part D plan, which includes a standalone Part D plan or an MA–PD plan. This proposed coordinating MA SEP may be used to disenroll from an MA plan to original Medicare, or to enroll in a MA plan that does not include Part D benefits, regardless of whether the individual uses the Part D IEP to enroll in a standalone Part D plan. The SEP would begin and end concurrently with the additional Part D IEP.

These previously proposed revisions would codify existing subregulatory guidance for SEPs that MA organizations have previously implemented and are currently following, except the SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer. We would also note that we are taking this opportunity to propose minor editorial changes in § 422.62(b) and (c), such as changing ''Original Medicare'' to ''original Medicare.''

2. Part D Special Election Periods (§ 423.38)

Section 1860D–1(b)(3) of the Act establishes special election periods (SEPs) during which, if certain circumstances exist, an individual may enroll in a stand-alone Part D prescription drug plan (PDP) or disenroll from a PDP and enroll in another PDP or in an MA plan that includes Part D benefits (MA–PD plan). We have codified SEPs for the following circumstances, which are explicitly discussed in the Act:

• The individual involuntarily loses creditable prescription drug coverage or such coverage is involuntarily reduced so that it is no longer creditable coverage (§ 423.38(c)(1) and section 1860D–1(b)(3)(A) of the Act).

• The individual was not adequately informed that he or she has lost his or her creditable prescription drug coverage that he or she never had credible prescription drug coverage, or the coverage is involuntarily reduced so that it is no longer creditable prescription drug coverage (§ 423.38(c)(2) and section 1860D–1(b)(3)(A) of the Act).

• The individual's enrollment or non-enrollment in a Part D plan is unintentional, inadvertent, or erroneous because of the error, misrepresentation, or inaction of a federal employee, or any person authorized by the federal government to act on its behalf (§ 423.38(c)(3) and section 1860D–1(b)(3)(B) of the Act).

• The individual is a full subsidy-eligible individual or other subsidy-eligible individual as defined in § 423.772, who is making an allowable one time-per-calendar-quarter election between January through September (§ 423.38(c)(4)) and section 1860D–1(b)(3)(D) of the Act).

• The individual elects to disenroll from a MA–PD plan and elects coverage under Medicare Part A and Part B in accordance with the MA special election period for individuals age 65 (§ 423.38(c)(5) and section 1860D–1(b)(3)(E) of the Act).

Section 1860D–1(b)(1)(B) of the Act directs us to adopt enrollment rules ''similar to (and coordinated with)'' those under Part C. Accordingly, in addition to those SEPs as previously described, we have applied certain SEPs established under the MA program to the Part D program. The SEPs from the MA program that have been codified for Part D include the following:

• The Part D plan sponsor's contract is terminated by the plan sponsor or by CMS or the plan is no longer offered in the area where the individual resides (§ 423.38(c)(6)).

• The individual is no longer eligible for the Part D plan because of a change in his or her place of residence to a location outside of the Part D plan region(s) in which the plan is offered (§ 423.38(c)(7)).

• The individual demonstrates to CMS that the plan sponsor substantially violated a material provision of its contract in relation to the individual (§ 423.38(c)(8)).

Section 1860D–1(b)(3)(C) of the Act also grants the Secretary the authority to create SEPs for individuals who meet other exceptional conditions, which is reflected at § 423.38(c)(8)(ii). Pursuant to this authority, we have previously codified SEPs for the following circumstances:

• The individual is making an election within 3 months after a gain, loss, or change to Medicaid or LIS eligibility, or notification of such a

change, whichever is later (§ 423.38(c)(9)). This would include becoming eligible for additional Medicaid benefits, for example, when an individual newly qualifies as needing nursing home level of care and thus becomes eligible for certain Medicaid long term supports and services, or becomes eligible for full Medicaid benefits after having previously been eligible only for Medicaid coverage of Medicare premiums or cost-sharing.

• The individual is making an election within 3 months after notification of a CMS or state-initiated enrollment action or that enrollment action's effective date, whichever is later (§ 423.38(c)(10)).

CMS now proposes to codify the following SEPs for exceptional circumstances, which are currently outlined in subregulatory guidance. Except as noted in this proposed rule, our intent is to codify the current policy, and we seek specific comment as to whether we have overlooked any feature of the current policy that should be codified and if there are other exceptional circumstances we have not identified for which we should consider establishing a special election period. Codifying our current policy for these SEPs will provide transparency and stability for stakeholders about the Part D program and about the nature and scope of these SEPs by ensuring that the SEPs are changed only through additional rulemaking. We are also proposing to revise § 423.40(c) to clarify that for SEPs that are described in § 423.38(c), elections are effective as of the first day of the first calendar month following the month in which the election is made, unless otherwise noted. In addition, we note that, consistent with longstanding subregulatory guidance, the organization is not required to contact an applicant to confirm SEP eligibility if the enrollment request includes the applicant's attestation of SEP eligibility.

• *SEP for Employer/Union Group Health Plan (EGHP) Elections.* At new § 423.38(c)(11), we are proposing to codify that individuals making enrollment requests into or out of employer sponsored Part D plans (PDPs), for individuals to disenroll from a PDP to take employer sponsored coverage of any kind, and for individuals disenrolling from employer sponsored coverage (including COBRA coverage) would be eligible for a SEP to elect a PDP.

This SEP is available to individuals who have (or are enrolling in) an employer or union plan for the duration of that enrollment and ends 2 months after the month the employer or union coverage ends. The individual may choose the effective date of enrollment or disenrollment, up to 3 months after the month in which the individual completes an enrollment or disenrollment request. However, the effective date may not be earlier than the first of the month following the month in which the request was made.

• *SEP for Individuals Who Disenroll in Connection With a CMS Sanction.* At new § 423.38(c)(12), we are proposing to codify the SEP for individuals enrolled in a PDP offered by a Part D plan sponsor that is sanctioned by CMS. Such enrollees would be eligible for a SEP to elect another PDP if they believe they are affected by the matter(s) that gave rise to that sanction. Once the sanction is imposed, we propose that CMS may require the sponsor to notify the current enrollees that if they believe they are affected by the matter that gave rise to the sanction, they are able to choose another PDP. The SEP starts with the imposition of the sanction and ends when the sanction ends or when the individual makes an election, whichever occurs first.

• *SEP for Individuals Enrolled in Cost Plans That Are Non-Renewing Their Contracts.* At new § 423.38(c)(13), we are proposing to codify the SEP for individuals enrolled in cost plans that are non-renewing their contracts for the area in which the enrollee lives. Such individuals would be eligible for a SEP to elect a PDP. This SEP would be available only to Medicare beneficiaries who are enrolled with an HMO or CMP under a section 1876 cost plan that will no longer be offered in the area in which the beneficiary lives. Beneficiaries electing to enroll in a PDP via this SEP must meet Part D plan eligibility requirements.

This SEP would begin December 8 of the current contract year and end on the last day of February of the following year. Therefore, applying the general rule we propose to codify that elections are effective the first of the month after they are made, enrollment requests received before December 31 would have an effective date of January 1, enrollment requests received between January 1 and January 31 would be effective February 1, and enrollment requests received between February 1 and February 28 (or 29, as the case may be) would be effective March 1.

• *SEP for Individuals in the Program of All-Inclusive Care for the Elderly (PACE).* At new § 423.38(c)(14), we are proposing to codify the SEP allowing individuals to disenroll from a PDP at any time in order to enroll in PACE. The PDP enrollee who disenrolls from a PDP would have a SEP for 2 months after the effective date of PDP disenrollment to elect a PACE plan. In addition, individuals who disenroll from PACE would have a SEP for 2 months after the effective date of PACE disenrollment to elect a PDP.

• *SEP for Institutionalized Individuals.* At new § 423.38(c)(15), we are proposing to codify the SEP allowing individuals who move into, reside in, or move out of an institution, as defined at § 422.2, to enroll in or disenroll from a PDP. Individuals who move out of one of these facilities would have a SEP to enroll in or disenroll from a Part D plan for 2 calendar months after they move out of the facility.

• *SEP for Individuals Who Enroll in Part B During the Part B General Enrollment Period (GEP).* At new § 423.38(c)(16), we are proposing to codify the SEP for individuals who are not entitled to premium free Part A and who enroll in Part B during the GEP for Part B (January–March) for an effective date of July 1st to enroll in a PDP. The SEP would begin April 1st and end June 30th, with an enrollment effective date of July 1st.

• *SEP for Individuals Who Belong to a Qualified SPAP or Who Lose SPAP Eligibility.* At new § 423.38(c)(17), we are proposing to codify a SEP for individuals who belong to a qualified SPAP to make one election to enroll in a Part D plan each calendar year. SPAP members, or the state acting as the authorized representative of members, may use this SEP to enroll in a Part D plan outside of existing enrollment opportunities, allowing them, for example, to join a Part D plan upon becoming a member of an SPAP or to switch to another Part D plan.

In addition to being available while the individual is enrolled in the SPAP, the SEP remains available for individuals no longer eligible for SPAP benefits for 2 months. The SEP continues until the month they lose SPAP eligibility or the month they are notified of the loss of SPAP eligibility, whichever is later, and then for an additional 2 months.

• *SEP for Disenrollment From Part D To Enroll in or Maintain Other Creditable Coverage.* At new § 423.38(c)(18), we are proposing to codify the SEP that provides an opportunity for individuals to disenroll from a Part D plan in order to enroll in or maintain other creditable drug coverage (such as TriCare or VA coverage) as defined in § 423.56(b). This SEP is available to a Part D plan enrollee who is enrolled in, or is enrolling in, other creditable drug coverage.

• *SEP for Individuals Disenrolling From a Cost Plan Who Also Had the Cost Plan Optional Supplemental Part D Benefit.* At new § 423.38(c)(19), we are proposing to codify that individuals who disenroll from a cost plan and the cost plan's optional supplemental Part D benefit would have a SEP to enroll in a PDP. This SEP would begin the month the individual requests disenrollment from the cost plan and end when the individual makes an enrollment election or on the last day of the second month following the month cost plan membership ended, whichever is earlier.

• *SEP To Enroll in a PDP with a Star Rating of 5 Stars.* At new § 423.38(c)(20), we are proposing to codify the SEP allowing an eligible individual to enroll in a PDP with a Star Rating of 5 stars during the plan contract year in which that plan has the 5-star overall rating. A rating of 5 stars is considered ''excellent'' and is the highest performance rating that a PDP can achieve. Because these PDPs have demonstrated exceptional performance, and because there tend to be only a small number of 5 Star PDPs in a given contract year, we believe a SEP is warranted to allow beneficiaries with access to these PDPs the opportunity to enroll during the plan year for which the 5 Star rating is applicable. The SEP is available beginning the first day after the AEP, December 8, prior to the plan contract year for which the 5 Star Rating is applicable, through November 30 of the plan contract year the 5 Star Rating is applicable. The enrollment effective date would be the first of the month following the month in which the plan sponsor receives the enrollment request.

An individual using this SEP would be able to enroll in a PDP with a 5-star overall rating even if coming from original Medicare. Individuals enrolled in a plan with a 5-star overall rating may also switch to a different plan with a 5-star overall rating.

• *SEP for Non-U.S. Citizens Who Become Lawfully Present.* At new § 423.38(c)(21), we are proposing to codify the SEP for non-U.S. citizens who become lawfully present in the United States. The individual may use this SEP to request enrollment in any PDP for which he or she is eligible. This SEP would begin the month the lawful presence starts and ends when the individual makes an enrollment election or at the end of the second calendar month after the month it begins, whichever occurs first.

• *SEP for Providing Individuals Who Requested Materials in Accessible Formats Equal Time To Make Enrollment Decisions.* As outlined in section 504 of the Rehabilitation Act of 1973, plan sponsors are required to comply with requirements of that Act and provide materials in accessible formats to members. This generally includes formats such as Braille, data, and audio files, or other formats accepted by the member in place of, or in addition to, the original print material.

At new § 423.38(c)(22), we are proposing to codify the SEP in situations where the Part D plan sponsor or CMS was unable to provide required notices or information in an accessible format, as requested by an individual, within the same timeframe that it was able to provide the same information to individuals who did not request an accessible format. This limited SEP ensures that beneficiaries who have requested information in accessible formats are not disadvantaged by any additional time necessary to fulfill their request, including missing an election period deadline.

The SEP would begin at the end of the election period during which the beneficiary was seeking to make an election. The start of the SEP, as well as the enrollment effective date, would be dependent upon the situation, and the length is at least as long as the time it took for the information to be provided to the individual in an accessible format. An individual would be eligible for this SEP when the conditions described in this section are met. Part D plan sponsors would be required to maintain adequate documentation of the situation, including records indicating the date of the individual's request, the amount of time taken to provide accessible versions of the requested materials and the amount of time it takes for the same information to be provided to an individual who does not request an accessible format.

• *SEP for Individuals Affected by a FEMA-Declared Weather Related Emergency or Major Disaster.* We are proposing to codify, at new § 423.38(c)(23), the SEP for individuals affected by a weather-related emergency or major disaster who were unable to make an election during another valid election period. This includes both enrollment and disenrollment elections. Individuals would be eligible for this SEP if they:

++ Reside, or resided at the start of the incident period, in an area for which FEMA has declared an emergency or a major disaster and has designated affected counties as being eligible to apply for individual or public level assistance;

++ Had another valid election period during the incident period; and

++ Did not make an election during that other valid election period due to the emergency or disaster.

In addition, the SEP would be available to those individuals who do not live in the affected areas but rely on help making healthcare decisions from friends or family members who live in the affected areas. The SEP would be available from the start of the incident period and for 4 months after the start of the incident period.

• *SEP for Individuals Enrolled in a Plan Placed in Receivership.* We propose to establish a new SEP, at new § 423.38(c)(31), for individuals enrolled in a Part D plans offered by a plan sponsor that is experiencing financial difficulties to such an extent that a state or territorial regulatory authority has placed the sponsor in receivership. We believe this SEP constitutes an exceptional circumstance because receiverships have the potential to cause disruption in access to prescription drug coverage and that individuals should have the ability to take action to prevent any future disruption to drug coverage. The SEP would allow an individual to discontinue the election of a PDP and change his or her election to a different PDP. We propose that the SEP begin the month the receivership is effective and continue until the enrollee makes an election or the receivership is no longer in effect, whichever occurs first.

Also, we propose that when instructed by CMS, the Part D plan sponsor that has been placed under receivership, or the entity operating the organization in receivership, must notify its enrollees, in the form and manner directed by CMS, of their eligibility for this SEP and how to use the SEP.

• *SEP for Individuals Enrolled in a Plan That Has Been Identified by CMS as a Consistent Poor Performer.* We propose to establish a new SEP, at new § 423.38(c)(32), for individuals who are enrolled in plans identified with the low performing icon (LPI) in accordance with § 423.186(h)(1)(ii). The LPI is assigned to contracts that have summary ratings of less than 3 Stars for three or more years. We believe this SEP constitutes an exceptional circumstance because these contracts have demonstrated performance considered ''below average'' or ''poor'' for a sustained period of time based on critical factors such as beneficiary complaints and access to care. To ensure that beneficiaries are not adversely affected, we believe that beneficiaries enrolled in these contracts should have the ability to enroll in plans rated ''average'' or higher during the year. The SEP would allow an

individual to discontinue the election of a consistently poor performing Part D plan and change his or her election to a Part D plan with an overall Star Rating of 3 or more stars. We propose that the SEP exist while the individual is enrolled in the consistently poor performing Part D plan.

• *SEP for Other Exceptional Circumstances.* Lastly, we propose to retain the authority currently at § 423.38(c)(8)(ii) to create SEPs for individuals who meet other exceptional conditions established by CMS and move it to new § 423.38(c)(33). SEPs established under this authority would only be done on a case-by-case basis and in situations which we determine it is in the best interest of the beneficiary to have an enrollment (or disenrollment) opportunity. While our experience with the Part D program has informed the SEPs that we have established to date, and are proposing to codify in this regulation, we are mindful that exceptional circumstances may arise which may also warrant a SEP, and we note that this list is not meant to be exhaustive.

Also based on the Secretary's authority to create SEPs for individuals who meet exceptional conditions, we propose to codify the following SEPs currently outlined in manual instructions that coordinate with Part C election periods:

• *SEP for Individuals Who Terminated a Medigap Policy When They Enrolled For the First Time in an MA Plan, and Who Are Still in a Trial Period.* Individuals who dropped a Medigap policy when they enrolled for the first time in an MA plan are provided a guaranteed right to purchase another Medigap policy if they disenroll from the MA plan while they are still in a ''trial period.'' In most cases, a trial period lasts for 12 months after a person enrolls in an MA plan for the first time. If the individual is using the SEP proposed at § 422.62(b)(8) to disenroll from a MA–PD plan, we are proposing to codify at new § 423.38(c)(24) a coordinating Part D SEP to permit a one-time enrollment into a PDP. This SEP opportunity may only be used in relation to the MA SEP described here and would begin the month he or she disenrolls from the MA plan and continue for 2 additional months.

• *SEP for an Individual Using the MA Open Enrollment Period for Institutionalized Individuals (OEPI) To Disenroll From a MA–PD plan.* Individuals who meet the definition of ''institutionalized'' as defined by CMS are eligible for the MA OEPI election period. At new § 423.38(c)(25), we are proposing to codify that an individual disenrolling from an MA–PD plan has a SEP to request enrollment in a PDP. This SEP would begin the month the individual requests disenrollment from the MA–PD plan and end on the last day of the second month following the month MA enrollment ended.

• *Medicare Advantage Open Enrollment Period (MA OEP).* At new § 423.38(c)(26), we are proposing to codify that MA enrollees using the MA OEP would have a SEP to add or change Part D coverage. Annually, the MA OEP is available from January 1 to March 31. It is also available for the first 3 months an individual has Medicare entitlement. An individual who elects original Medicare during the MA OEP would be able to request enrollment in a PDP during this time.

• *SEP To Request Enrollment Into a PDP After Loss of Special Needs Status or To Disenroll From a PDP in Order To Enroll in an MA SNP.* In new § 423.38(c)(27), we propose to codify the SEP to request enrollment in a PDP for those who are no longer eligible for a SNP because they no longer meet the plan's special needs criteria. In addition, CMS would provide a SEP to allow for disenrollment from a PDP at any time in order to request enrollment in an MA SNP. For example, if state eligibility criteria for a D–SNP is limited to individuals who are enrolled in a Medicaid MCO affiliated with the D–SNP, then disenrollment from the Medicaid MCO would trigger eligibility for this SEP. This SEP would begin the month the individual's special needs status changes and end when he or she makes an election or 3 months after the effective date of the involuntary disenrollment, whichever is earlier.

• *SEP for Enrollment Into a Chronic Care SNP and for Individuals Found Ineligible for a Chronic Care SNP.* At proposed § 423.38(c)(28), we propose to codify the SEP for both Part C and Part D for those individuals with severe or disabling chronic conditions to enroll in a Chronic Care SNP (C–SNP) designed to serve individuals with those conditions. This SEP would apply as long as the individual has the qualifying condition and will end once s/he enrolls in a C–SNP. Once the SEP ends, that individual may make enrollment changes only during applicable election periods. In addition, individuals enrolled in a C–SNP who have a severe or disabling chronic condition that is not a focus of their current C–SNP would be eligible for this SEP to change to a C–SNP that does focus on the condition that the individual has. Eligibility for this SEP would end at the time the individual enrolls in the new C–SNP.

Individuals who are found after enrollment into a Chronic Care SNP not to have the required qualifying condition would have a SEP to enroll in a different MA–PD plan or an MA-only plan with accompanying Part D coverage, if allowed. This SEP would begin when the plan notifies the individual of the lack of eligibility and extends through the end of that month, plus 2 additional months. The SEP would end when the individual makes an enrollment election or on the last day of the second month following notification.

• *SEP for Individuals Using the 5-Star SEP To Enroll in a 5-Star Plan without Part D Coverage.* At new § 423.38(c)(29), we are proposing to codify that individuals who use the 5-star SEP proposed to be codified at § 422.62(b)(15) to enroll in a 5-star MA plan that does not include Part D benefits or a 5-star cost plan would have a SEP to enroll in a PDP or in the cost plan's optional supplemental Part D benefit. The PDP selected using this coordinating SEP does not have to be 5-Star rated. However, individuals may not use this coordinating SEP to disenroll from the plan in which they enrolled using the 5-star SEP.

This SEP would begin the month the individual uses the 5-Star SEP and continue for 2 additional months. Individuals who use the 5-Star SEP to enroll in an MA coordinated care plan would not be eligible for this coordinating Part D SEP and must wait until their next valid election period in order to enroll in a plan with Part D coverage.

• *SEP To Enroll in a PDP for MA Enrollees Using the ''SEP for Significant Change in Provider Network'' To Disenroll From an MA Plan.* We are proposing to codify at new § 423.38(c)(30) that MA enrollees using the ''SEP for Significant Change in Provider Network'' to disenroll from an MA plan (proposed at § 422.62(b)(23)) would be able to request enrollment in a PDP. This coordinating SEP would begin the month the individual is notified of eligibility for the SEP and continue for an additional 2 calendar months. This SEP would permit one enrollment and end when the individual has enrolled in the PDP. An individual may use this SEP to request enrollment in a PDP subsequent to having submitted a disenrollment to the MA plan or may simply request enrollment in the PDP, resulting in automatic disenrollment from the MA plan. Enrollment in the PDP is effective the first day of the month after the plan sponsor receives the enrollment request.

These proposed revisions would codify existing subregulatory guidance for SEPs that Part D sponsors have previously implemented and are currently following, except for the *SEP for Individuals Enrolled in a Plan Placed in Receivership* and the *SEP for Individuals Enrolled in a Plan that has been Identified by CMS as a Consistent Poor Performer.* We would also note that we are taking this opportunity to propose a few minor editorial changes in § 423.38(c), such as changing ''3'' to ''three.''

VII. Proposed Changes to the Programs of All-Inclusive Care for the Elderly (PACE)

The intent of this proposed rule is to revise and update the requirements for the Programs of All-Inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs. The PACE program is a unique model of managed care service delivery for the frail elderly, most of whom are dually-eligible for Medicare and Medicaid benefits, and all of whom are assessed as being eligible for nursing home placement according to the Medicaid standards established by their respective states. The proposals address reassessments, service delivery requests, appeals, participant rights, required services, excluded services, interdisciplinary team requirements, medical record documentation, access to data and records, safeguarding communications, and service delivery requirements. The proposed changes would reduce unnecessary burden on PACE organizations, provide more detail about CMS expectations and provide more transparent guidance.

A. Service Delivery Request Processes Under PACE (§§ 460.104 and 460.121)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify that PACE organizations must have in effect written safeguards of the rights of enrolled participants, including procedures for grievances and appeals. We issued regulations on grievances at § 460.120, and we issued regulations on appeals at § 460.122. Additionally, CMS created a process under § 460.104(d)(2) to allow participants or their designated representatives to request that the interdisciplinary team (IDT) conduct a reassessment, when the participant or designated representative believes the participant needs to initiate, eliminate or continue a service. The process under § 460.104(d)(2) is commonly referred to by CMS and industry as the service delivery request process. This process serves as an important participant protection, as it allows a participant to advocate for services. As we stated in the Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE); Program Revisions; Final Rule (hereinafter referred to as the 2006 PACE final rule), ''[t]he provisions for reassessment at the request of a participant [were] intended to serve as the first stage of the appeals process.'' 71 FR 71292. Section 460.104(d)(2) currently sets out the responsibilities of a PACE organization in processing each request. Currently, a participant or their designated representative initiates a service delivery request when they request to initiate, eliminate, or continue a service. Once the IDT receives the request, the appropriate members of the IDT, as identified by the IDT, must conduct a reassessment. The IDT member(s) may conduct the reassessment via remote technology when the IDT determines that the use of remote technology is appropriate and the service request will likely be deemed necessary to improve or maintain the participant's overall health status and the participant or their designated representative agrees to the use of remote technology. However, the appropriate member(s) of the IDT must perform an in-person reassessment when the participant or their designated representative declines the use of remote technology, or before a PACE organization can deny a service request. Following the reassessment, the IDT must notify the participant or designated representative of its decision to approve or deny the request as expeditiously as the participant's condition requires, but generally no later than 72 hours from the date of the request for reassessment. If the request is denied, the PACE organization is responsible for explaining the denial to the participant or the participant's designated representative both orally and in writing. The PACE organization is also responsible for informing the participant of his or her right to appeal the decision, including the right to request an expedited appeal, as specified in § 460.122. If the IDT fails to provide the participant with timely notice of the resolution of the request, or does not furnish the services required by the revised plan of care, the failure constitutes an adverse decision and the participant's request must be automatically processed as an appeal in accordance with § 460.122.

While this section provides an important participant protection, we have heard from stakeholders that the language in § 460.104(d)(2) is overly broad as written, and that even simple requests to initiate a service require a reassessment and a full review of the request by the PACE organization's IDT. Stakeholders have also noted that addressing the service delivery request process in the section of the regulation governing participant assessments undercuts the importance of the requirements for processing these requests. Additionally, through CMS oversight and monitoring, we have identified a need to better define what constitutes a service delivery request and create clearer guidance on how PACE organizations must identify and process these requests.

We are proposing to move the requirements for service delivery requests at § 460.104(d)(2) to a new section of the regulations at § 460.121, titled ''Service Delivery Requests.'' While we are proposing to use the term ''service delivery request'' because that is the term typically used by industry and CMS to describe these actions, we are soliciting comments on whether we should utilize this term or consider something different. For example, the initial decision to cover a drug in Part D is a coverage determination (§ 423.566), and the initial decision to cover an item or service in Part C is an organization determination (§ 422.566). We would appreciate feedback on whether a term other than ''Service Delivery Request,'' such as ''PACE Organization Determination,'' ''Coverage Determination,'' or ''Service Determination,'' would be preferable.

In addition to proposing that the requirements for processing service delivery requests would be moved from § 460.104(d)(2) into a new section, we are also proposing to modify these requirements based on industry feedback and lessons learned through our experience operating the PACE program and monitoring PACE organizations. First, we are proposing to reorganize the requirements for clarity and to better align them with the appeals regulations in subpart M of parts 422 and 423, for Medicare Advantage (MA) and Part D respectively, while also ensuring the requirements address the specific features of the PACE program, which is a unique combination of payer and direct care provider. We believe aligning the layout of the regulation and the notification requirements of the initial determination processes in PACE, MA, and Part D would allow us to minimize confusion for participants, who are often familiar with the initial determination and appeals processes in the Parts C and D programs, and would also increase transparency for PACE organizations regarding CMS' expectations.

While the current regulation at § 460.104(d)(2) begins with the requirements for processing a request for reassessment, we are proposing to add § 460.121(a) to require that a PACE organization must have formal written procedures for identifying and processing service delivery requests in accordance with the requirements of proposed § 460.121. We believe it is important to ensure that PACE organizations develop internal processes and procedures to properly implement this process.

At § 460.121(b), we are proposing to define what constitutes a service delivery request and what does not. We are proposing to define what constitutes a service delivery request at § 460.121(b)(1). Currently, the process in § 460.104(d)(2) is triggered if the participant (or his or her designated representative) believes the participant needs to initiate, eliminate, or continue a particular service. At § 460.121(b)(1), we are proposing to specify that the process for service delivery requests would apply to three distinct types of service delivery requests, specifically, a request to (1) initiate, (2) modify, or (3) continue a service.

We note that the term ''services'' is already defined at 460.6 to include ''items,'' and we are proposing, as discussed in section VII.I. of this proposed rule, to make explicit that this definition is meant to reflect the full scope of the PACE benefit package, and thus also includes ''items'' and ''drugs.'' Therefore, our use of ''service'' or ''services'' throughout newly proposed 460.121 always includes any type of PACE-covered services, items, or drugs, and participants have the right to advocate with respect to all types of PACE-covered services, items, or drugs that they believe may be necessary. The proposed language at § 460.121(b)(1) would retain the existing concepts of '''initiating'' and ''continuing'' services but would replace the term ''eliminate'' with the term ''modify.''

We are proposing at § 460.121(b)(1)(i) that the first type of service delivery request would be a request to initiate a service. This first type of request is based on the existing language at § 460.104(d)(2). We are proposing at § 460.121(b)(1)(ii) that the second type of service delivery request would be a request to modify an existing service. We are proposing to specify that requests to modify an existing service include requests to increase, reduce, eliminate, or otherwise change a particular service. We believe that defining service delivery requests to include requests to modify an existing service is an important protection, as participants may believe that the services they are currently receiving are not sufficient to meet their needs. For example, a participant may request to increase their home care from 3 hours a week to 6 hours a week because they believe that they are becoming less steady in their gait and they are afraid to be alone for long periods.

The third type of service delivery request we are proposing, at § 460.121(b)(1)(iii), is a request to continue a service that the PACE organization is recommending be discontinued or reduced. We are proposing that this type of request would apply to circumstances where the PACE organization is recommending to discontinue or reduce a service that the participant is already receiving, and the participant wishes to continue receiving that service. An example of this type of request would be a participant that is attending the PACE center 5 days a week and the PACE organization decides to reduce attendance to 4 days a week. If the participant requests to continue attending the center 5 days a week, this request must be processed as a service delivery request under our proposal. Another example would be if a participant is receiving a specific drug, and the IDT makes a decision to stop providing that drug. Under this proposal, the participant's request to continue receiving the drug would be processed as a service delivery request. Through our monitoring of PACE organizations, we have identified instances where a participant requests to continue receiving a service that has been reduced or discontinued, and the PACE organization provides the participant appeal rights under § 460.122 instead of conducting a reassessment as required under the current § 460.104(d)(2). We are proposing to include requests to continue coverage of a service in part to ensure that PACE organizations understand that they must process a service delivery request for these situations before processing an appeal under § 460.122. Our proposed revisions to this section, as well as our proposed revisions to the appeals regulation discussed in section VII.B. of this proposed rule, would establish that the service delivery request process is the first level of the appeals process, and requests to continue a service must first be processed under the service delivery request process prior to an appeal being initiated under § 460.122. We discuss the scope of the appeals process in greater depth in our proposals to update the appeals process in section VII.B. of this proposed rule. We are also proposing that participants would be allowed to make this type of service delivery request before a service was actually discontinued, to permit the participant to advocate for a continuation of the service. This requirement is reflected in the language we propose for § 460.121(b)(1)(iii), where we emphasize that this provision relates to a service that the PACE organization is recommending be discontinued or reduced. We believe by wording this requirement in this way, we would make clear that the participant could make a service delivery request as soon as a PACE organization recommends reducing or discontinuing a service. For example, if the IDT was recommending reducing center attendance from three days a week to two days a week, and the participant wanted to continue coming to the center three days a week, the participant could request a service delivery request once the IDT recommended the reduction, even if the reduction in days had not yet been implemented.

We recognize that our proposals define what constitutes a service delivery request broadly. We also understand that there are circumstances that are unique to PACE where a request may not constitute a service delivery request based on the role of a PACE organization as a direct care provider that is responsible for coordinating and delivering care. We are therefore proposing an exception to the definition of a service delivery request. In paragraph (b)(2) we are proposing that certain requests to initiate, modify, or continue a service would not constitute a service delivery request, even if the request would otherwise meet the definition of a service delivery request under (b)(1). Specifically, at § 460.121(b)(2) we are proposing that if a request is made prior to the development of the initial care plan the request would not constitute a service delivery request. This exemption would apply any time before the initial care plan was finalized (and discussions amongst the IDT ceased). We believe this approach would be beneficial to the participant and the PACE organization as the IDT and the participant or caregiver continue to discuss the comprehensive plan of care taking into account all aspects of the participant's condition as well as the participant's wishes. For example, if the PACE organization is developing the initial plan of care and actively considering how many home care hours the participant should receive, and the participant makes a request for a

particular number of home care hours, that request would not be a service delivery request because the IDT was actively considering that question in developing the plan of care. Once the initial plan of care is developed, if a service was not incorporated into the plan of care in a way that satisfies the participant, the participant would always have the right to make a service delivery request at that time.

While drafting this proposal, we considered other ways to potentially limit the application of the service delivery request process to account for situations where it is possible to adequately address a request without undertaking the full service delivery request process. First, we considered excluding requests for services made during the course of a treatment discussion with a member of the IDT from the service delivery request process, so long as the IDT member is able to immediately approve the service. Ultimately we decided these situations should constitute service delivery requests, in order to avoid confusion by requiring PACE organizations to distinguish between requests for services that constitute service delivery requests and those that do not. However, in an effort to reduce burden, we determined that it would be appropriate to process service delivery requests that an IDT member is able to approve in full at the time the request is made in a more streamlined manner than other service delivery requests. We discuss our proposals on this point in more detail in the section relating to proposed § 460.121(e)(2) in this proposed rule.

We also considered whether we could exclude other types of requests from the service delivery request process. For example, we have received questions from PACE organizations about requests that do not relate to health care or to a participant's medical, physical, emotional, and social needs, such as a participant requesting lemons in their water, or a participant requesting a particular condiment at lunch. We considered proposing to exclude requests that are not related to health care or to the participant's medical, physical, emotional, and social needs, and therefore would not constitute a service delivery request. We strongly believe that any time a service may be necessary to maintain or improve the participant's overall health status, taking into account the participant's medical, physical, emotional, and social needs, that request should be processed as a service delivery request. We similarly understand that some requests are completely unrelated to the participant's health care or condition. However, we believe that adding a provision to address this relatively insignificant issue would potentially cause confusion for PACE organizations and participants and therefore we are not proposing such a provision at this time. We are, however, soliciting comments on whether specifying that requests unrelated to a participant's medical, physical, emotional, and social needs need not be processed using the proposed service delivery request process would benefit PACE organizations without restricting participants' ability to advocate for any service they believe may be necessary, regardless of whether that is meals, transportation, drugs, home care, or other services provided as part of the PACE benefit, and if so, how we should word such a provision.

We are also proposing at § 460.121(c) to specify the individuals who can make a service delivery request. Under the current requirements in § 460.104(d)(2), only the participant or the participant's designated representative may request to initiate, eliminate, or continue a particular service. We are proposing to expand the number of individuals who can make a service delivery request on behalf of a PACE participant to include the participant, the participant's designated representative, or the participant's caregivers. We believe that this proposal would be consistent with the current practice of most PACE organizations, in part because caregivers are often also participants' designated representatives; however, we are proposing to affirmatively state in regulation that these individuals may make service delivery requests. We believe this would provide an important safeguard for participants, as caregivers are usually aware of the participant's situation and have valuable insight into what services would be beneficial. For example, if a PACE participant's wife believes that the participant needs more home care to assist with toileting, bathing and dressing, we are proposing that she would be able to make a service delivery request to the PACE organization and advocate for that service delivery request, regardless of whether she is her spouse's designated representative. This proposal also aligns with current care plan regulations which state that the IDT must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver or both. (§ 460.106(e)) Because caregivers are involved in the care planning process and determining what care may be necessary, we believe that it is also appropriate for these individuals to be able to advocate for services as necessary on behalf of a participant, regardless of whether these service delivery requests result in changes to the plan of care. While a designated representative or caregiver such as a family member may initiate the service delivery request process, the PACE organization remains responsible for issuing a decision based on the individual needs of the participant regardless of the party that initiated the request. We are soliciting comments on this proposal to expand the number of individuals who can make a service delivery request on behalf of a PACE participant. In addition we are soliciting comment regarding whether or not there are other individuals that should be allowed to make service delivery requests on behalf of a participant. For example, in MA and Part D, providers or prescribers can initiate a request for coverage (either coverage determination or organization determination) on behalf of a beneficiary, which allows prescribers or other providers to advocate for drugs or services that are unique to their discipline or scope of practice. In PACE, this would mean that if a participant went to a contracted specialist, that specialist would be allowed to advocate or request a service specific to their discipline. We are specifically soliciting comments on whether we should specify that prescribers or providers, outside of the IDT, can make a service delivery request on behalf of a participant in PACE.

We are also proposing at § 460.121(d) to specify how a service delivery request may be made. The current regulation at § 460.104(d)(2) is silent regarding how a participant or his or her designated representative may request to initiate, eliminate, or continue a particular service. We are proposing at § 460.121(d)(1) to permit service delivery requests to be made either orally or in writing. We believe this is consistent with current practice for all PACE organizations. The right to request an initial determination either orally or in writing is provided as an enrollee safeguard in both MA and Part D (see §§ 422.568(a)(1), 422.570(b), 423.568(a)(1), and 423.570(b)), and given the vulnerability of the PACE population, we believe it is important that PACE participants also have the ability to submit service delivery requests in either form. We are proposing at § 460.121(d)(2) that service delivery requests may be made to any individual who provides direct care to a participant on behalf of the PACE organization, whether as an employee or a contractor, as contemplated in

§ 460.71. All employees and contractors that provide direct participant care should be trained to recognize and document these requests when they are made by a participant. Because of the comprehensive nature of the PACE program and the requirement that PACE organizations provide care across all care settings, participants may not know whom they should communicate with when making a service delivery request. For example, certain participants may not attend the PACE center on a routine basis and a home care aide may be the only representative of the PACE organization the participant has contact with frequently. Under our proposal, the participant could make service delivery requests to the home care aide, and those requests would be considered to have been made to the PACE organization. All individuals providing direct care to participants, whether contractors or employees, should be trained to recognize service delivery requests and ensure such requests are documented appropriately and brought to the IDT as part of the training employees and contractors receive under § 460.71(a)(1). While we are proposing to require that all contractors and employees that provide direct care be able to receive service delivery requests from participants, we are soliciting comment on whether this requirement should be limited to a smaller subset of individuals. For example, we seek comment on whether we should instead require only those contractors or employees who provide direct participant care in the participant's residence, the PACE center, or while transporting participants to receive service delivery requests.

CMS is also proposing to establish new requirements at § 460.121(e) specifying how service delivery requests must be processed. We are proposing at § 460.121(e)(1) that all service delivery requests must be brought to the IDT as expeditiously as the participant's condition requires, but no later than 3 calendar days after the date the request was made. The existing requirement at § 460.104(d)(2)(iii) specifies that the IDT must generally notify the participant or designated representative of its decision in regard to a request to initiate, eliminate, or continue a particular service no later than 72 hours after the date the IDT receives the request for reassessment. Stakeholders have asked CMS to explain if the current 72-hour timeframe begins when any member of the IDT receives the service delivery request, or when the full IDT receives the request. In order to avoid similar questions about the new service delivery request process we are proposing, we have also proposed to establish two distinct timeframes. Specifically, we are proposing an initial timeframe for the PACE organization to bring a service delivery request to the IDT, and a second timeframe for the IDT to make a decision and provide notice of the decision to the participant. We are proposing to include this second timeframe at § 460.121(i), and discuss this proposal in more detail later in this section. We believe that creating these distinct timeframes would benefit both PACE organizations and participants. We also believe it is necessary to ensure that once a service delivery request is made, it is brought to the IDT for processing as expeditiously as the participant's condition requires but no later than 3 calendar days from when the request was actually made. In monitoring PACE organizations, we have seen organizations take a week or longer after a request was first made to bring the request to the IDT for consideration. By establishing a requirement that service delivery requests must be brought to the IDT as expeditiously as the participant's condition requires but no later than 3 calendar days from the time the request is made, we believe this would ensure participant requests are handled expeditiously while still ensuring the IDT has sufficient time to process the service delivery request and consider all relevant information when making a decision. We are soliciting comments on this proposal to establish a new timeframe for PACE organizations to bring service delivery requests to the IDT.

We are also proposing at § 460.121(e)(2) to specify an exception to the processing requirements for service delivery requests. Specifically, if a member of the IDT receives a service delivery request and is able to approve the request in full at the time the request is made, the PACE organization would not be required to follow certain processing requirements. We understand that PACE organizations, as direct care providers, routinely interact with participants when providing care and services. These interactions often include treatment discussions between an IDT member and a participant about what care may or may not be appropriate for the participant to receive. During these discussions, a participant may request a service that the IDT member receiving the request is able to immediately approve as requested based on their knowledge of the participant and the participant's condition. For example, during a physical therapy session, a participant may request a walker to assist in his or her daily activities. If the physical therapist, who is a member of the IDT, determines that the item is necessary and can approve the walker at the time the participant requests it, then the request would not need to be processed as a normal service delivery request. The exception would not apply if the IDT member cannot approve exactly what is requested. For example, if a participant requested 20 hours per week of home care but the IDT member is only willing to approve 15 hours per week, the exception would not apply because the participant's request would be partially denied. Specifically, we are proposing at § 460.121(e)(2)(i) to require that when a member of the IDT can approve a service delivery request in full at the time the request is made, the PACE organization must fulfill only the requirements in proposed paragraphs (j)(1), (k), and (m). These proposed paragraphs are discussed in more detail later in this section, and generally relate to notice of a decision to approve a service delivery request, effectuation requirements, and record keeping. We are also proposing at § 460.121(e)(2)(ii) that PACE organizations would not be required to process these particular service delivery request in accordance with paragraphs (f) through (i), paragraph (j)(2), or paragraph (l) of this new section, all of which are discussed in more detail in this section of this proposed rule.

We are proposing this exception to how a service delivery request is processed based on feedback from stakeholders that IDT members often have treatment discussions with participants about modifying services and make decisions to accommodate the participants' requests in full at the time the requests are made. Additionally, we have seen situations where a caregiver requests an item or service that an IDT member is able to immediately approve at the time the request is made. In these situations, it is important that the decision to approve the service is communicated to the participant or the requestor at the time the request is made so that the participant/requestor understands the outcome of their request. If a decision to approve a requested service cannot be made in full at the time of the request, the PACE organization must fully process the service delivery request in accordance with all relevant paragraphs of this new section. If an IDT member can quickly approve a service as being necessary for the participant, we do not believe that

it would benefit the participant or the organization to have to fully process a service delivery request, since the participant or requestor has already been successful in advocating for the service. Instead, the participant would be better served by the IDT member quickly communicating the approval, and working to provide the requested service as expeditiously as the participant's condition requires. We want to note that pursuant to our proposal in § 460.121(d)(2), a service delivery request may be made to any contractor or employee who provides direct care to a participant, and that all individuals providing direct care to participants, whether contractors or employees, should be trained to recognize and receive service delivery requests pursuant to § 460.71(a)(1). However, we are proposing to specifically limit the exception in § 460.121(e)(2) to requests made to IDT members, where the receiving member of the IDT is able to approve the service delivery request in full at the time the request is made. This will ensure that the IDT remains responsible for determining the benefits a participant should receive, and that contractors or employees, such as a home care aide, are not authorizing services without the IDT's review.

We also believe this proposed exception at § 460.121(e)(2) would reduce the current burden on PACE organizations in three primary ways. First, PACE organizations would not have to bring requests that can be quickly approved by one IDT member to the full IDT for consideration and discussion, which would allow the IDT to use that time for other purposes, including to focus on requests that require in-depth consideration. Second, because the IDT would not have to conduct a reassessment in each case, we expect that this change would improve the overall speed with which PACE organizations are able to provide necessary services. Third, the IDT would not have to provide separate notification to the participant because the IDT member would inform the participant or requestor that the request was approved in the initial discussion.

Currently the IDT is required to process requests for reassessments from participants and/or designated representatives under § 460.104(d)(2). The IDT is responsible for selecting the appropriate IDT members to conduct the reassessment under § 460.104(d)(2), and for issuing a decision to approve or deny a request under § 460.104(d)(2)(iii). At proposed § 460.121(f), we would require that all service delivery requests, other than those under proposed § 460.121(e)(2), must be brought to the full IDT for review and discussion before the IDT makes a determination to approve, deny or partially deny the request. As required by § 460.102(b), each PACE organization's IDT must, at a minimum, be composed of members qualified to fill the roles of 11 disciplines, each of which offers a unique perspective on the participant's condition. CMS commonly refers to this group as the full IDT. Because service delivery requests not processed under proposed § 460.121(e)(2) are processed only for services that cannot be approved in full at the time the request is received, we believe that it is important that the IDT, as a whole, discuss the service delivery request in order to determine whether the request should be approved or denied. A discussion by the full IDT would allow each discipline to offer their perspective on the participant's condition as it relates to the requested service, and ensure that the IDT is best equipped to determine what services are necessary to improve or maintain the participant's health status. As previously discussed, service delivery requests that are approved in full by a member of the IDT at the time the request is made would not have to be brought to the full IDT for review.

We are also proposing at § 460.121(g) to require that the IDT must consider all relevant information when evaluating a service delivery request. Currently, the regulation is silent on what the IDT must consider when making a decision under § 460.104(d)(2). We are proposing that the IDT must consider, at a minimum, the findings and results of any reassessment(s) conducted in response to a service delivery request, as well as the criteria used to determine required services specified in proposed § 460.92(b), as discussed in section VII.D. of this proposed rule. We have seen through our monitoring efforts that certain IDTs do not always consider the reassessments conducted in response to a service delivery request when making a decision. For example, a physical therapist and occupational therapist may both indicate in their discipline-specific reassessments that a participant would benefit from additional home care hours, but the IDT might deny the request without explaining why the recommendations resulting from those reassessments were not followed. We believe it is important that an IDT is able to demonstrate that it took any reassessments performed in the process of reviewing a service delivery request into consideration when making a decision on that service delivery request. Additionally, we believe that IDT decision making for service delivery requests should be aligned with the IDT's decision making for what constitutes a required service under § 460.92(b). Specifically, we believe that a decision by the IDT to provide or deny services must be based on an evaluation of the participant that takes into account the participant's medical, physical, emotional and social needs. We have encountered situations where the IDT made its decision based on one aspect of the participant's condition, for example, their physical health related to their ability to perform activities of daily living, but disregarded other aspects of the participant's condition, such as their medical, emotional, and social needs. We believe that the IDT must consider all aspects of the participant's condition in order to make an appropriate decision. For example, if the participant is requesting to attend the PACE center on additional days due to feelings of social isolation and depression, it would be inappropriate for the IDT to make a decision based on the participant's physical needs without considering their emotional and social needs. Additionally, under the proposed modifications to § 460.92, we would also expect PACE organizations to utilize current clinical practice guidelines and professional standards of care when rendering decisions, as applicable to a requested service. We discuss this decision making process and use of these guidelines in more detail in section VII.D. of this proposed rule.

Based on feedback from PACE organizations and advocacy groups, we are proposing at § 460.121(h) to require an in-person reassessment only prior to an IDT's decision to deny or partially deny a service delivery request. Currently, the IDT must perform a reassessment as part of its consideration of any request to initiate, eliminate, or continue a service under § 460.104(d)(2), regardless of whether the request is approved or denied. We modified the requirements related to conducting reassessments in response to a participant or designated representative's request to initiate, eliminate, or continue a service in the 2019 PACE Final Rule (84 FR 25644 through 25646). The regulations now permit the IDT to conduct that reassessment via remote technology if certain requirements are met, but the IDT must conduct an in-person reassessment prior to denying a request. However, since that rule was published on June 3, 2019, we have continued to receive feedback from PACE

organizations requesting further action to address the burden of conducting reassessments in response to service delivery requests, specifically when the IDT can approve a request without performing a reassessment. Under our proposal, if a service delivery request is brought to the full IDT and the IDT determines that it can approve the request based on the information available, the IDT would not be required to conduct a reassessment of the participant prior to making a decision to approve the service delivery request. We understand that many IDTs have frequent interactions with PACE participants and may be able to make a decision to approve a request without having to conduct another reassessment based on internal consultation and knowledge of the participant. As we indicated in our discussion for the proposed § 460.121(e)(2), we do not believe that delaying the provision of a requested service the IDT has determined is necessary, in order to conduct a reassessment, benefits the PACE organization or the participant. We believe the IDT, with its knowledge of the participant, is in the best position to determine if a reassessment is necessary prior to approving a service delivery request. Therefore CMS would only require a reassessment prior to the IDT denying or partially denying a request under this proposal.

If, after consideration of all available information, the full IDT expects to make a decision to deny or partially deny a service delivery request, we are proposing that the IDT would be required to perform an unscheduled in-person reassessment pursuant to proposed § 460.121(h)(1), prior to making a final decision. We are proposing to consider a request denied or partially denied whenever the IDT makes a decision that does not fully approve the service delivery request as originally requested. For example, if a participant requested 3 hours of home care a week, and the IDT made a decision that the participant only required 2.5 hours of home care each week, we are proposing that such a decision by the IDT would constitute a partial denial because the request was not fully approved as requested by the participant. In other words, any decision to offer a compromise, an alternative service, or to grant only a portion of the request would constitute a partial denial. We are proposing that this in-person reassessment must be conducted by the appropriate members of the IDT, as identified by the IDT, in order to align with the current requirement under § 460.104(d)(2) that the IDT is responsible for identifying the appropriate members to conduct the reassessment. We believe this change would strike an appropriate balance between protecting participants and ensuring that the process for handling service delivery requests is not overly burdensome for PACE organizations.

We are also proposing in § 460.121(h)(1) to require that any reassessment conducted for a service delivery request must evaluate whether the requested service is necessary to meet the participant's medical, physical, emotional, and social needs in a manner consistent with § 460.92, as we are proposing to revise those provisions. We have seen through our monitoring efforts that in conducting reassessments as a result of requests to initiate, eliminate or continue particular services, the IDTs are not always evaluating whether the requested service would actually improve or maintain the participant's condition, taking into account all relevant aspects of the participant's condition, including assessing the participant's medical, physical, emotional and/or social needs as applicable. We believe this information is vital, and must be considered by the full IDT in making its decision. For example, if a participant is requesting more days at the PACE center for social reasons, the IDT should ensure that the appropriate members of the IDT conduct the reassessment in order to evaluate the participant's social needs, and whether additional center days are necessary to meet the participant's needs, including improving the participant's social condition. We discuss our proposals for § 460.92 in greater detail in section VII.D. of this proposed rule.

In accordance with our belief that the IDT is in the best position to determine if a reassessment is necessary prior to approving a service delivery request, we are proposing at § 460.121(h)(2) that the IDT may choose to conduct a reassessment (via either remote technology or in-person) before approving a service delivery request, but we do not believe we should require one as part of the process for approving service delivery requests. If the IDT determines a reassessment should be conducted prior to approving the request, the IDT would still be responsible for processing the service delivery request, and notifying the participant, in the timeframe specified at § 460.121(i).

We are proposing at paragraph (i) to establish a time frame in which the IDT must make its determinations regarding service delivery requests and provide notification of its decisions. The current requirement under § 460.104(d)(2)(iii) states that the IDT must notify the participant or designated representative of its decision to approve or deny a service delivery request as expeditiously as the participant's condition requires, but no later than 72 hours after the date the IDT receives the request, unless the IDT extends the timeframe. CMS has interpreted this language as requiring that the IDT must notify the participant or their designated representative within 3 calendar days of receiving a request, based on the wording of the requirement which states ''72 hours from the date'' and thus requires that the timeframe starts on the day received.

We are proposing a similar timeframe at § 460.121(i), to require that the IDT make its determination and notify the participant or their designated representative of the determination as expeditiously as the participant's health condition requires, but no later than 3 calendar days after the date the IDT receives the request. We continue to believe this is a reasonable timeframe for the IDT to discuss the request, conduct reassessments when required, and make a decision. The IDT is currently allowed to extend the timeframe for notifying a participant or their designated representative by no more than 5 additional days under § 460.104(d)(2)(iv). Extensions are currently permitted when the participant or designated representative requests an extension, or when the IDT documents its need for additional information and how the delay is in the interest of the participant. We are proposing in § 460.121(i)(1) to include a similar provision for extensions, which would allow the IDT to extend the timeframe for review by up to 5 calendar days beyond the original deadline in certain circumstances. We are proposing at § 460.121(i)(1)(i) that the IDT may extend the timeline for review and notification if the participant or other requestor listed in § 460.121(c)(2) or (3) requests the extension. We are proposing to change designated representative to requestor to account for the proposed change we made in § 460.121(c) regarding who can make a service delivery request, and including caregivers in situations where that person may not already be a designated representative. We believe that the participant or other requestor should be able to request an extension. For example, the participant may be out of town and the caregiver may request the IDT to take an extension in order for the participant to be in-person for the reassessment related to the request.

We are proposing at § 460.121(i)(1)(ii) that the IDT can extend the timeframe

for review and notification when the extension is in the best interest of the participant due to the IDT's need to obtain additional information from an individual who is not directly employed by the PACE organization, and that information may change the IDT's decision to deny a service. We believe it is important that the IDT does not routinely take extensions when the participant or other requestor has not asked for one. We understand that when the IDT has to obtain information from individuals not employed directly by the organization, it may be difficult to get timely responses. We also understand that obtaining this information is beneficial for the IDT and the participant in order to ensure that the IDT has sufficient information to make a decision on whether or not a service should be approved. For example, if the IDT is considering a request for dentures, information from the participant's dentist would be relevant to the review, and the IDT may need to take an extension if the dentist does not respond within the initial 3 calendar days. However, we believe it is important that PACE organizations develop processes to ensure prompt decisions about service delivery requests, and that IDTs do not routinely or unnecessarily rely on extensions of the notification timeframe, such as when information can be obtained from an employee of the PACE organization. We are also proposing, for extensions based on the need for additional information, to apply the requirements currently in § 460.104(d)(2)(iv)(B) that require the IDT to document the circumstances that led to the extension and to demonstrate why the extension is in the participant's interest. We are proposing to add a new requirement at § 460.121(i)(2) to require the IDT to notify the participant or the designated representative in writing, as expeditiously as the participant's condition requires but no later than 24 hours after the IDT extends the timeframe, and to explain the reason(s) for the delay. We are proposing to require that the notification of the extension must occur within 24 hours from the time the IDT makes the decision to extend the timeframe because we believe it is important that participants or their designated representatives understand that a decision may be delayed and why, especially if the extension was taken by the IDT.

In addition, we are proposing to add requirements at § 460.121(j) related to notifying the participant or the designated representative of the IDT's decision to approve, deny, or partially deny a service delivery request. Currently, IDTs are required to notify the participant or their designated representative of the decision to approve or deny a request under § 460.104(d)(2)(iii). As we previously discussed, in relation to our proposals under § 460.121(c), we are proposing to expand the number of individuals who can make a service delivery request. However, we are not proposing to change the individuals whom the IDT would notify of its decision to approve or deny the service delivery request. We believe that in all circumstances, the participant (or designated representative) should receive the notification of the IDT's decision to approve or deny the service delivery request. In the rare situation where a caregiver, such as a family member, is not the designated representative, notification of the service delivery request would be sent to either the participant or designated representative, and not the family member. As always, under current § 460.102(f), the PACE organization remains responsible for establishing, implementing and maintaining documented internal procedures that govern the exchange of information between participants and their caregivers consistent with the requirements for confidentiality in § 460.200(e). We would expect that PACE organizations, as a part of that documented process, have a method for determining when notification should go to the participant versus a representative (including a caregiver).

We are proposing at paragraph (j)(1) to specify the notification requirements when the IDT approves a service delivery request. Specifically, we are proposing to require the IDT to notify the participant or the designated representative of that decision either orally or in writing. We are proposing that the notification must explain any conditions for the approval in understandable language, including when the participant may expect to receive the approved service. We believe it is important that the IDT explain to the participant or their designated representative any conditions that may apply whenever the IDT approves a service delivery request. For example, if the IDT is approving a service delivery request for home care, the IDT should indicate the days and hours that are being approved and when the home care would start.

For service delivery requests that can be approved in full at the time the request is made under proposed § 460.121(e)(2), the IDT member who approves the request would be responsible for ensuring that the notification satisfies the proposed requirements in new § 460.121(j)(1). Because a request must be able to be approved in full at the time the participant makes the request under this provision, the IDT member who approves the service would be responsible for providing notification, and ensuring that the conditions of the approval (if any) are explained to the participant. While we allow for the IDT to provide approval notification either orally or in writing, because decisions under § 460.121(e)(2) are made in real time, and communicated to the participant at the time the request is made, we do not believe written notification would be necessary in these instances; however, a PACE organization may always choose to send written notification following the oral notification in order to memorialize any conditions of the approval.

We are also proposing at § 460.121(j)(2) provisions similar to those currently set forth in § 460.104(d)(2)(v), to require that PACE organizations must notify participants or the designated representative of a decision to deny or partially deny a service delivery request both orally and in writing. We believe that the requirement to notify the participant or their designated representative both orally and in writing should be maintained to ensure participants or their designated representatives receive and understand the denial. We are also proposing to expand upon the specific requirements for what a denial notice must contain. At § 460.121(j)(2)(i) we are proposing to require that the IDT state the specific reasons for the denial, including an explanation of why the service is not necessary to improve or maintain the participant's overall health status. Under this proposal, the rationale for the denial would have to be specific to the participant, taking the participant's medical, physical, emotional, and social needs into account, and it would include the results of any reassessment(s) conducted by the PACE organization. The rationale would have to be stated in understandable language so that the participant or designated representative can comprehend why the request was denied. We believe that it is important to continue to require that the IDT provide the specific reasons for a denial. However, based on our experiences monitoring PACE organizations, we believe we need to propose more detailed requirements about what the explanation of the specific reason(s) for the denial should include. Providing

this explanation for a denial would allow the participant or their designated representative to more fully understand why the IDT determined a requested service was not necessary. This would also allow a participant or designated representative to better understand what information they may need to provide if they appeal the denial.

At § 460.121(j)(2)(ii) and (iii), we are proposing to retain the requirements currently codified in § 460.104(d)(2)(v)(A) and (B) that the PACE organization inform the participant or designated representative of the right to appeal any denied service delivery request as specified in § 460.122; and that the PACE organization must also describe the process for both standard and expedited appeals, and the conditions for obtaining an expedited appeal. Additionally, with minor modifications, we are proposing to retain a requirement similar to current § 460.104(d)(2)(v)(C): The PACE organization would be required to notify Medicaid participants about their right to, and the conditions for, continuing to receive a disputed service through the duration of the appeal. Medicaid participants include all participants that are enrolled in Medicaid only or both Medicaid and Medicare (dually eligible). Currently, § 460.104(d)(2)(v)(C) cross-references all of § 460.122(e), but we believe that a more tailored reference to § 460.122(e) would be preferable. We are therefore proposing to cross-reference only § 460.122(e)(1) at proposed § 460.121(j)(2)(iv), because the information provided in § 460.122(e)(2) relates to the PACE organization's continued responsibility to continue to furnish to participants all required services other than the disputed service, and is not specifically about continuing to receive the disputed service. We do not believe we need to require that the IDT include information from § 460.122(e)(2) in a service delivery request denial notification because this concept is widely understood and could potentially confuse participants if they received notification of that requirement. However, we solicit comments on whether it would be preferable to retain a cross-reference to all of § 460.122(e).

We are proposing at § 460.121(k) to specify the timeframe in which the PACE organization must provide services approved, in whole or in part, through the service delivery request process. We are proposing to require the PACE organization to provide the requested service as expeditiously as the participant's condition requires, taking into account the participant's medical, physical, emotional, and social needs. We are not proposing a specific timeframe due to the many varying types of services that PACE organizations provide. However, we expect PACE organizations to develop processes to help them identify how quickly they need to provide a service based on the participant's condition. For example, we would generally expect that a drug used to treat a participant's diabetes would be provided much more quickly than we would expect a dental cleaning to be provided. That is because a treatment for diabetes may require a more immediate response, whereas a dental cleaning may not be as urgent. We recognize that not all services can be physically provided in a rapid timeframe, however, we do expect that the PACE organization take prompt action to ensure the approved service is provided as expeditiously as needed. Additionally, for services that can be approved under proposed § 460.121(e)(2), while we require that the IDT member be able to approve the request in full at the time the request is made, we do not require that the approved service be physically provided at the time the request is made. Instead, we are proposing that those approved service delivery requests must also be effectuated under the requirements in this proposed section.

The current requirement at § 460.104(d)(2)(vi) states that the PACE organization must automatically process a participant's request as an appeal when the IDT fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care. We are proposing to retain this requirement, unaltered, at § 460.121(l). We continue to believe that this is an important safeguard for participants to ensure they have access to the appeals process, even when a PACE organization does not adhere to the processing requirements under the rules of this part.

We are proposing at paragraph (m) to add requirements that would address record keeping for service delivery requests. While PACE organizations are currently required to document all assessments under § 460.104(f), we believe that it would be important to have a separate section in the new § 460.121 that more specifically addresses the record keeping requirements, to help ensure that PACE organizations accurately document and track all service delivery requests and have a complete and accurate record of each request and how it was resolved. We are proposing at § 460.121(m) that PACE organizations must establish and implement a process to document, track, and maintain records related to all processing requirements for service delivery requests. We are also proposing to specify that PACE organizations must account for, and document, requests received both orally and in writing. PACE participants often call PACE organizations and request a service over the phone, and it is important for the PACE organization to have an established process to accurately document and track those verbal requests, along with requests submitted to the organization in writing. Once a PACE organization receives a service delivery request, the PACE organization would be responsible for documenting, tracking and maintaining all records that relate to the processing of the service delivery request, including but not limited to, the IDT discussion, any reassessments conducted, all notification that was provided to the participant or designated representative, and the provision of the approved service, when applicable. These documentation requirements would apply to all service delivery requests, including service delivery requests that can be approved in full at the time the request is made per proposed § 460.121(e)(2). Additionally, as we mention in our discussion of § 460.200(d) at section VII.C. of this proposed rule, we are proposing to require that documentation be safeguarded against alteration, and that written requests for services must be maintained in their original form. We are also proposing to require that these records must be available to the IDT to ensure that all members remain alert to pertinent participant information.

Because we are proposing to define the requirements for service delivery requests in the new § 460.121, we propose to remove all requirements relating to service delivery requests from the current § 460.104(d)(2). Specifically, we are removing § 460.104(d)(2)(i) through (v) and we are proposing to modify the existing language in § 460.104(d)(2) to reiterate that the PACE organization must conduct an in-person reassessment if it expects to deny or partially deny a service delivery request. Additionally, as we discussed in § 460.121(h)(2), the IDT may conduct a reassessment as determined necessary for services it intends to approve. We are proposing to modify language in 460.104(d)(2) to direct readers to the new § 460.121(h) for the requirements regarding conducting reassessments in response to service delivery requests.

B. Appeals Requirements Under PACE (§§ 460.122 and 460.124)

As discussed previously, sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act require PACE organizations to have in effect written safeguards of the rights of enrolled participants, including procedures for grievances and appeals. In the preamble to Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE) Interim Final Rule (hereinafter referred to as the 1999 PACE interim final rule), which was published in the **Federal Register** on November 24, 1999 (64 FR 66234), CMS explained that we considered the appeals requirements under what is now MA when creating the appeals requirements for PACE (see 64 FR 66257–66258). CMS established the requirements for PACE organizations' appeals processes in §§ 460.122 (PACE organization's appeals process) and 460.124 (Additional appeal rights under Medicare or Medicaid). Over time, PACE organizations have asked CMS to explain certain aspects of the appeals processes described in §§ 460.122 and 460.124. We are therefore proposing certain changes to §§ 460.122 and 460.124 that would provide additional detail about the appeals process and help ensure consistency in the administration of the appeals process among PACE organizations. We are also proposing a few other changes to increase beneficiary awareness of and access to the appeals process, and to align with other changes proposed in this rule. The term ''appeal'' is currently defined in § 460.122 as a participant's action taken with respect to the PACE organization's noncoverage of, or nonpayment for, a service including denials, reductions, or termination of services. We are proposing to add a sentence after the definition to require that PACE organizations must process all requests to initiate, modify or continue a service as a service delivery request before processing an appeal under § 460.122. As we discussed in VII.A. of this proposed rule, we have seen through audits that some PACE organizations will process an appeal instead of processing a service delivery request when a participant makes a request to continue receiving a service that the PACE organization is discontinuing or reducing. We are proposing to add a sentence to this introductory paragraph in order to affirmatively require that all requests that satisfy the definition of a service delivery request under § 460.121(b) must first be processed as such before a PACE organization may process an appeal. Section 460.122(b) currently provides that upon enrollment, at least annually thereafter, and whenever the IDT denies a request for services or payment, the PACE organization must give a participant written information on the appeals process. Consistent with the changes that we are proposing to existing § 460.104(d)(2) and new § 460.121, which are discussed in section VII.A. of this proposed rule, we are proposing to modify § 460.122(b) to specify that PACE organizations must provide participants with written information on the appeals process at enrollment, at least annually thereafter, and whenever the IDT denies a service delivery request or other request for services or payment. By proposing this change, CMS is seeking to ensure that participants consistently and timely receive information about their appeal rights, including when PACE organizations deny their service delivery requests.

Section 460.122(c) provides requirements for the minimum written procedures that PACE organizations must establish for their appeals process. We have heard that these requirements have created confusion among PACE organizations, which has led to inconsistent implementation among PACE organizations and a lack of participant awareness of and participation in the appeals process. As a result, we are proposing a number of changes to decrease confusion and increase beneficiary awareness of and access to the appeals process.

We are proposing two modifications at paragraph (c)(2). First, we are proposing to add a participant's designated representative as someone who has the right to appeal on the participant's behalf. We believe that this is an important participant safeguard because it allows for assistance in navigating the appeals process. Additionally, we are proposing that in developing procedures for how a participant or a participant's designated representative files an appeal, PACE organizations would be required to include procedures for receiving oral and written appeal requests. Because of the comprehensive nature of the care PACE organizations provide, participants are likely to have more verbal interactions with staff of the PACE organization and may express their desire to appeal a decision, but may be unsure or confused as to how. We believe that by requiring PACE organizations to accept appeal requests made both orally and in writing, we would create an important safeguard for the participant population enrolled in the PACE program. By allowing both oral and written requests for appeals, this proposal would enhance participant access to the appeals process, and to services covered under the PACE benefit.

Second, in response to questions received from PACE organizations, we are proposing to add language in paragraph (c)(4) to specify the qualifications required of an appropriate third party reviewer or members of a review committee. Specifically, we are proposing changes to require PACE organizations to ensure appeals are reviewed by an appropriate reviewer or committee. This includes separating the requirements that an appropriate third party reviewer and the members of a review committee must be ''independent'' and ''appropriately credentialed'' to emphasize the fact that an appropriate third party reviewer or member of a review committee must be both independent and appropriately credentialed. We discuss the use of a review committee in the preamble to the 2006 PACE final rule (see 71 FR 71302) and PACE organizations currently utilize review committees in their review processes; therefore, we have proposed to incorporate review committees in regulation at this time and require the members of review committees to satisfy the same requirements as appropriate third party reviewers. Employees or contractors may participate in review committees as long as they meet the requirements set forth in proposed § 460.122(c)(4). Consistent with the current requirements at § 460.122(c)(4), we are proposing to specify that in order to be an appropriate third party reviewer or member of a review committee, an individual must be an impartial third party who was not involved in the original action and does not have a stake in the outcome of the appeal. We are also proposing to add language that more clearly defines an appropriately credentialed reviewer. As we discussed in the preamble to the 2006 final rule, the appropriate third party reviewer must be someone with expertise in the appropriate field. Thus it would not be appropriate for a social worker to review an appeal related to a physical therapy denial; nor would it be appropriate for a gynecologist to review a denial of services relating to coronary surgery. 71 FR 71302.

Therefore, we are proposing to modify the language in paragraph (c)(4) to specify that an appropriate third party reviewer is one who is credentialed in a field or discipline related to the appeal. We do not believe that these proposals would affect the way PACE organizations currently choose their third party reviewers since the existing

regulation at § 460.122(c)(4) requires the appointment of an appropriately credentialed and impartial third party that was not involved in the original action and who does not have a stake in the outcome of the appeal to review the participant's appeal. By proposing amendments to expressly state that the same requirements also apply to the members of a review committee, we believe that this proposal would give PACE organizations more clarity and flexibility to utilize resources within the organization as well as contracted employees.

PACE organizations have expressed confusion about the third party review process, and we are aware of inconsistent decisions made by third party reviewers. In order to reduce confusion, create a more consistent application of Medicare and Medicaid coverage requirements under PACE, and increase consistency for participants, we are proposing additional modifications to the requirements under § 460.122(c). Specifically, we are proposing to add a new paragraph (c)(5) that would require PACE organizations to take specific steps to ensure their third party reviewers understand the PACE benefit package and the coverage requirements under the PACE program, and how to review requests in a manner consistent with both. As noted in the preamble to the 2006 PACE final rule at 71 FR 71302, PACE organizations should ensure that credentialed and impartial third party reviewers are trained to make decisions in a manner similar to the determinations under section 1862(a)(1)(A) of the Act. Such determinations would be based on the participant's medical needs and not on other reasons such as the cost of the disputed care, who is paying the third party reviewer's salary or fee, an individual's reputation, or other factors. We are therefore proposing, in new paragraph (c)(5), to require PACE organizations to provide written or electronic materials to an appropriate third party reviewer(s) that, at a minimum, explain that services must be provided in a manner consistent with the requirements in §§ 460.92 and 460.98, the need to make decisions in a manner consistent with determinations made under section 1862(a)(1)(A) of the Act, and the requirements in § 460.90(a) that specify that many of the limitations on the provision of services under Medicare or Medicaid do not apply in PACE.

The requirements for providing appeal notifications are at § 460.122(d) and currently provide that a PACE organization must give all parties involved in the appeal (1) appropriate written notification and (2) a reasonable opportunity to present evidence related to the dispute, in person, as well as in writing. However, PACE organizations have expressed that this section of the regulation is confusing because it discusses both the notification requirements and the participant's opportunity to submit evidence during an appeal. To reduce confusion, we are proposing to separate these requirements. Accordingly, we are proposing to redesignate paragraph (g) as (h) and also change the title of paragraph (h) to ''Actions following a favorable decision.'' This redesignation allows for the addition of the proposed new paragraph (g) that sets forth notification requirements. We also propose to modify paragraph (d) to address the existing requirement that the PACE organization must give all parties involved in the appeal a reasonable opportunity to present evidence related to the dispute in person as well as in writing. At new paragraph (g), we are proposing to revise the notice requirements for appeals to more closely align with the proposed notice requirements for service delivery requests at § 460.121(j) by specifying the content of the notice in order to ensure consistency and minimize confusion for PACE organizations and participants. We are proposing that PACE organizations would be required to give all parties involved in the appeal (for example participants or their designated representatives) appropriate written notice of all appeal decisions. In the case of appeal decisions that are favorable to the participant, the PACE organization would be required to explain any conditions on the approval in understandable language. For partially or fully adverse decisions, the PACE organization would be required to state the specific reason(s) for the denial, explain the reason(s) why the service would not improve or maintain the participant's overall health status, inform the participant of his or her right to appeal the decision, and describe the additional appeal rights under § 460.124. Conditions of approval may include, but are not limited to, the duration of the approval, limitations associated with an approval such as dosage or strength of a drug, or any coverage rules that may apply. We are also proposing to revise and move the current requirements at paragraph (h) into new paragraph (g)(2)(ii). These requirements specify that for determinations that are wholly or partially adverse to a participant, at the same time the decision is made, the PACE organization must notify CMS, the State administering agency, and the participant. Because this paragraph includes additional notification requirements that PACE organizations must follow after a decision is made to deny an appeal, we believe that this belongs in proposed § 460.122(g)(2) for notice of adverse decisions. We are also proposing to revise this requirement to use terminology consistent with our other proposed amendments to § 460.122, specifically, to refer to ''partially or fully adverse'' decisions and to refer to an appeal decision rather than to a determination for consistency with proposed § 460.122(g)(2)(i) and other sections of this regulation.

We are also proposing a few minor changes to align with other changes proposed in this rule. First, we are proposing to change the reference to § 460.104(d)(2)(iv) in § 460.122(c)(1) to reference the service delivery request requirements in § 460.121(i) and (m). The current citation references the extension requirements for unscheduled reassessments; however, we believe that this reference should have been to the general timeframes for processing service delivery requests. We are also proposing to redesignate the current paragraphs (c)(5) and (6) as (c)(6) and (7) in § 460.122 to allow for the addition of a new paragraph (c)(5), as discussed earlier in this section.

Lastly, we are proposing to add language to § 460.124 that delineates the additional appeal rights that PACE participants are entitled to receive under Medicare or Medicaid and add processing requirements for the PACE organization. In response to comments CMS received on the 1999 PACE interim final rule, CMS discussed stakeholder concerns about the PACE appeals process in the preamble to the 2006 PACE final rule and reiterated the intended process in the preamble. See 71 FR 71303–71304. Specifically, CMS stated in the preamble to the 2006 PACE final rule that Medicare beneficiaries have access to the Medicare external appeals route through the IRE that contracts with CMS to resolve MA appeals, while Medicaid eligible participants have access to the State Fair Hearing (SFH) process. See 71 FR 71303. However, despite this clarification, CMS's audits have revealed that PACE organizations continue to misinterpret the requirements under § 460.124 relating to participants' additional appeal rights under Medicare or Medicaid. To address this issue, we are proposing several changes to § 460.124. First, we are proposing to add new paragraphs (a) and (b) at § 460.124. We are proposing at § 460.124(a) to specify that Medicare

participants have the right to a reconsideration by an independent review entity (IRE). We recognize that there are differences in the terminology used in PACE versus MA and therefore have proposed to add similar language at new § 460.124(a)(1), (2), and (3) to establish in regulation the requirements for how an appeal may be made to the independent, outside entity, the timeframe in which the independent outside entity must conduct the review, and who are the parties to the appeal. At proposed § 460.124(a) introductory text and (a)(1) we have intended to parallel the requirements at § 422.592(a) with minor differences. Under MA there is automatic escalation to the independent review entity at this level of appeal if the organization upholds its adverse decision, in whole or in part. However, in PACE, appeals are not automatically escalated because most PACE participants are dually eligible for Medicare and Medicaid benefits and these participants may choose to utilize the Medicaid or Medicare route for independent review. For these dually eligible individuals, it may be more appropriate to pursue an appeal through the Medicaid path rather than the Medicare path. The provisions relating to automatic-escalation in MA ensure that the beneficiary receives a review by an independent reviewer; however, this protection is not necessary in PACE as the PACE participant has already received an independent review on the appeal during the internal appeal processed in accordance with § 460.122. We are therefore proposing at § 460.122(a)(1) to specify that a written request for a reconsideration must be filed with the independent review entity within 60 calendar days of the decision by the third party reviewer. We did not specify who must file the request because we discuss at § 460.124 that the PACE organization must assist the participant in choosing which appeal rights to pursue (that is, Medicaid SFH or Medicare IRE) and as such, we believe that the PACE organization is also responsible for ensuring that the request is filed with the appropriate external entity. However, a participant always maintains the right to file a request without assistance from the PACE organization. At § 460.124(a)(2) we are proposing to add a requirement that the independent review entity must conduct the review as expeditiously as the participant's health condition requires but must not exceed the deadlines specified in the contract. The independent review entity is currently operating under these timeframes, consistent with the requirements at § 422.592(b), and participants are currently utilizing the independent review entity to exercise their external appeal right, consistent with CMS's historical interpretation that these requirements are applicable to the PACE program. We have also proposed the addition of language at § 460.124(a)(3) that would parallel the requirement at § 422.592(c), to specify that when the independent review entity conducts a reconsideration, the parties to the reconsideration are the same parties described in § 460.122(c)(2), with the addition of the PACE organization. We are seeking to enhance transparency and we believe it is important to make PACE organizations aware that they are considered a party to the appeal once it reaches the independent review entity. We are also proposing to add a new paragraph (b) that specifies that Medicaid participants have the right to a SFH as described in part 431, subpart E. Finally, we are proposing a new paragraph (c) to specify that participants who are dually eligible for both Medicare and Medicaid have the right to external review by means of either the IRE or the SFH process. This provision would specify that dually eligible participants may choose to pursue an appeal through either the Medicare or Medicaid process. In accordance with § 460.124, PACE organizations must assist dual eligible participants in choosing which route to pursue if both the IRE and the SFH review processes are applicable. For example, if the appeal is related to an enrollment dispute, the Medicaid SFH process would be the appropriate route for a participant to pursue. Whereas for a dispute related to a Part D medication, the IRE would be the appropriate route for a participant to pursue. By codifying these appeal rights in regulation, we are seeking to enhance transparency for PACE organizations to ensure that participants are able to access additional levels of appeal in order to receive services they believe that they are entitled to under the PACE benefit.

C. Access to Data and Safeguarding Records Under PACE (§ 460.200)

In accordance with sections 1894(e)(3)(A) and 1934(e)(3)(A) of the Act, § 460.200 requires PACE organizations to collect data, maintain records, and submit reports, as required by CMS and the State Administering Agency (SAA). The current requirement at § 460.200(b) requires that PACE organizations must allow CMS and the SAA access to data and records, including but not limited to, participant health outcomes data, financial books and records, medical records, and personnel records. Some PACE organizations have asked for clarification on whether access is limited to allowing CMS or the SAA to view requested information. CMS has long interpreted this provision to require that CMS and the SAA must be able to obtain, examine, or retrieve information as needed to administer and evaluate the program and fulfill their oversight obligations. Therefore, we are proposing to codify CMS' interpretation of this requirement. Specifically, we are proposing to redesignate current § 460.200(b)(1) through (4) as § 460.200(b)(1)(i) through (iv), in order to add a new paragraph (b)(2) to state that CMS and the State administering agency (SAA) must be able to obtain, examine, or retrieve the information described under § 460.200(b)(1). This may include CMS or the SAA reviewing information at the PACE site or remotely. It may also include CMS requiring a PACE organization to upload or electronically transmit information, or send hard copies of required information by mail.

PACE organizations are also required to safeguard data and records in accordance with § 460.200(d). This section currently provides that a PACE organization must establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration. Through our monitoring of PACE organizations, CMS has discovered that PACE organizations do not always maintain and safeguard important records such as communications related to a participant's care from family members, caregivers, and the participant's community. In fact, CMS has discovered that organizations may summarize written communications and sometimes destroy or lose original written communications. When CMS has obtained copies of original communications from an outside source (such as the family or caregiver), we have noted that organizations are not accurately summarizing information or retaining the relevant information in the communication. In light of these findings, we believe that any written communication received from a participant or their informal support (for example, a family member, caregiver, designated representative, or other member of the community) that relates to the participant's care, health or safety must be safeguarded and maintained in its original form. Therefore, we are proposing to modify § 460.200(d) to require PACE organizations to maintain all written communications received

from a participant or other parties in their original form when the communication relates to the participant's care, health, or safety. We would expect that this would include most, if not all, communications that an organization receives on these topics. For example, the following types of communications would need to be protected under this provision: Written requests for services that the participant, designated representative or caregiver believes are necessary; grievances or complaints relating to the participant's care or health; and communications from the community that indicate concerns over the well-being of a PACE participant. We are proposing corresponding changes to § 460.210(b)(6), to require PACE organizations to maintain original written communications in the participant's medical record, as discussed at section VII.F. of this proposed rule.

We believe the burden associated with this provision is related to the documentation of these original communications in the medical record. We discuss and account for the burden of documenting these communications in the medical record in the regulatory impact analysis.

We are soliciting comments on these proposals.

D. PACE Services, Excluded PACE Services, and the Interdisciplinary Team (§§ 460.92, 460.96, and 460.102)

1. Required Services

Sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act state that the PACE program provides comprehensive health care services to PACE participants in accordance with the PACE program agreement and regulations under those sections. Sections 1894(b) and 1934(b) of the Act set forth the scope of benefits and beneficiary safeguards under PACE. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act specify in part that PACE organizations must provide participants, at a minimum, all items and services covered under titles XVIII and XIX of the Act without any limitation or condition as to amount, duration, or scope, and all additional items and services specified in regulations, based upon those required under the PACE protocol.[94] CMS codified these required services in § 460.92 of the regulations, which provides that the PACE benefit package for all participants, regardless of the source of payment, must include all Medicare covered items and services, all Medicaid covered items and services, as specified in the State's approved Medicaid plan, and other services determined necessary by the interdisciplinary team (IDT) to improve and maintain the participant's overall health status.

We are proposing to modify the requirements at § 460.92 to more clearly define required services, and to specify CMS' expectations for making decisions about the services that are required under the PACE benefit package. First, we are proposing to create a new paragraph (a) and include under (a) the current requirements in § 460.92. In order to do that, we propose to renumber existing paragraphs (a), (b), and (c) as (a)(1), (2), and (3). We are proposing to add a new paragraph (b) that provides the standards that the IDT must consider when evaluating whether to provide or deny services described under (a) for a participant.

In addition to redesignating § 460.92(a) as § 460.92(a)(1), we are proposing to modify the language to refer to all Medicare-covered services. In light of our proposed amendments to the definition of ''services'' in § 460.6, and the current definition of that term, PACE organizations should understand that providing necessary drugs, whether they are covered under Medicare Parts A, B, or D, is an important part of the PACE benefit package. See section VII.I. of this proposed rule for a more detailed discussion of the definition of ''services.''

CMS is also proposing to add a new paragraph (b) in order to specify the standards that the IDT must consider when evaluating whether to provide or deny services required under § 460.92(a) for a participant. Under proposed § 460.92(b)(1) we are proposing to require the IDT to take into account all aspects of a participant's condition, including the participant's medical, physical, emotional, and social needs, when determining whether to approve or deny a request for a service. As we discussed in section VII.A. of this proposed rule, the determination for a service should be based on all aspects of the participant's care. For example, additional center days may not be necessary when considering the participant's physical needs, but when taking into account the participant's social needs, the IDT may find that those services become necessary in order to improve the participant's social or emotional condition. We have discovered through audits that PACE organizations sometimes only consider the medical or physical needs of a participant but do not consider their social or emotional needs when those social or emotional needs are relevant to the request.

We are also proposing to add language at § 460.92(b)(2) that would require organizations to utilize current clinical practice guidelines and professional standards of care when making a decision, so long as those guidelines and standards are applicable to the particular service. PACE organizations are currently required to utilize current clinical practice guidelines and professional practice standards when developing the outcome measures for their quality improvement programs at § 460.134(b). When we discussed this requirement in the preamble to the 1999 PACE interim final rule, we stated that we expect that PACE organizations will utilize current clinical standards as a routine part of their daily operations and care management strategies. (See 64 FR 66260). However, we have discovered through our PACE audits that decisions to deny services are sometimes not based on accepted clinical guidelines or standards. We understand that current clinical practice guidelines and professional standards of care may vary based on the type of service that is being considered. For example, when determining if a participant requires a cardiac catheterization, the organization may reference clinical practice guidelines issued by the American Heart Association. On the other hand, when determining the appropriate insulin for a participant the organization may appropriately refer to guidelines published by the American Diabetic Association. We also understand that certain services may not have an applicable clinical practice guideline. For example, determining the frequency of PACE center attendance may not be based on clinical practice guidelines, but may instead be based on the medical, physical, emotional, and social needs of the participant. Therefore, we are proposing to add language to (b)(2) to require the IDT to take into account current clinical practice guidelines and professional standards of care if applicable to a particular service. By adding this requirement, we do not intend to restrict a PACE organization's ability to determine what service is appropriate or necessary for a participant: The IDT would remain responsible for determining the participant's overall health status and needs, and ensuring those needs are met through the provision of necessary services.

We are not scoring this provision in the Regulatory Impact Analysis section because PACE organizations are already required to utilize current clinical

[94] The original PACE protocol was replaced by the PACE program agreement (84 FR 25613).

practice guidelines as a part of their quality improvement program, and they are required to consider the participant's physical, medical, emotional and social needs as a part of care planning discussions. We believe that by modifying this provision we will not be increasing burden on PACE organizations, as they already consider these items on a routine basis.

2. Excluded Services

As we stated earlier in this section, in the discussion regarding Required Services, the PACE benefit package includes all Medicare-covered items and services, all Medicaid-covered items and services, as specified in the state's approved Medicaid plan, and other services determined necessary by the IDT to improve or maintain the participant's overall health status. The regulations at § 460.96 list a number of services that are excluded from coverage under PACE. Currently, paragraph (a) states that any service that is not authorized by the IDT, even if it is a required service, is an excluded service unless it is an emergency service. In addition, paragraph (b) states that in an inpatient facility, private room and private duty nursing services (unless medically necessary), and nonmedical items for personal convenience such as telephone charges and radio or television rental are also excluded from coverage under PACE unless specifically authorized by the IDT as part of the participant's plan of care. We are proposing to remove § 460.96(a) and (b).

These proposals are consistent with our authority to amend the regulations. The exclusions in § 460.96 are not specifically listed in the PACE statute. They were included in the 1999 PACE interim final rule that implemented the PACE program in part because they were included in section A.6 of the PACE Protocol included as Addendum A to the 1999 PACE interim final rule. See 64 FR 66247 and 66301 and subparagraphs 1894(f)(2)(A) and 1934(f)(2)(A) of the Act. Sections 1894(f)(1) and 1934(f)(1) of the Act give the Secretary the authority to issue regulations to carry out the PACE program created under sections 1934 and 1894 of the Act. Sections 1894(f)(2) and 1934(f)(2) of the Act state that, in issuing such regulations the Secretary shall, to the extent consistent with the provisions of sections 1894 and 1934 of the Act, incorporate the requirements applied to PACE demonstration waiver programs under the PACE protocol. As we stated in the 2019 PACE final rule, we believe sections 1894(f) and 1934(f) of the Act primarily apply to issuance of the initial interim and final PACE program regulations because they refer to the PACE Protocol,[95] which has now been replaced by the PACE program agreement.[96] 84 FR 25613. Sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act permit the Secretary to modify or waive provisions of the PACE Protocol as long as any such modification or waiver is not inconsistent with and does not impair any of the essential elements, objectives, and requirements under sections 1894 or 1934 of the Act, but precludes the Secretary from modifying or waiving any of the following provisions:

- The focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.
- The delivery of comprehensive integrated acute and long-term care services.
- The IDT approach to care management and service delivery.
- Capitated, integrated financing that allows the PACE organization to pool payments received from public and private programs and individuals.
- The assumption by the PACE organization of full financial risk.

Taking this authority into account, we are proposing to remove 460.96(a) for the following reasons. CMS has gained a significant amount of experience with the PACE program since the 1999 PACE interim final rule, and we now believe that a number of PACE organizations are interpreting the exclusion under § 460.96(a) in a manner that is not consistent with sections 1894 and 1934 of the Act. Many PACE organizations appear to be interpreting § 460.96(a) to allow an IDT to exclude from coverage any service that the IDT does not authorize for a participant, even if it is clearly covered under the Medicare or Medicaid programs and is medically necessary. For example, CMS has identified through audits that some PACE organizations have denied certain types of covered Part D drugs for participants, even when the drug is medically necessary and the participant is qualified to receive the drug under Medicare.

These denials are inconsistent with the statutory requirement under sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act to provide all items and services covered by Medicare and Medicaid, as well as all additional items and services specified in regulations. As we stated in the 2006 PACE final rule, in accordance with sections 1894 and 1934 of the Act, PACE organizations shall provide all medically necessary services including prescription drugs, without any limitation or condition as to amount, duration, or scope and without application of deductibles, copayments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid. 71 FR 71248. PACE organizations are required to provide all Medicare covered services and all Medicaid covered services in accordance with the State's approved Medicaid plan under current § 460.92(a) and (b). In addition, PACE organizations are required to cover other items and services that are determined necessary by the IDT to improve and maintain the participant's overall health status under current § 460.92(c). In order to ensure that IDTs continue to make decisions that are consistent with the statutory requirements, we are proposing to remove paragraph (a) from § 460.96. We believe that removing paragraph (a) is necessary in order to ensure that participants receive the services to which they are entitled under PACE.

By proposing to remove paragraph (a), we do not intend to waive or eliminate the IDT approach to care management and service delivery. The IDT's authority and responsibility are defined throughout the PACE regulations, and under this proposed amendment, the IDT would retain its ability to determine which services are appropriate for a participant, and would remain responsible for coordinating the care of participants 24 hours a day, every day of the year. Additionally, as discussed in our proposed changes to § 460.92, we are proposing that the IDT's decision to provide or deny required services must be based on an evaluation of the participant that takes into account the participant's current medical, physical, emotional and social needs, along with any current clinical practice guidelines and professional standards of care that are applicable to the particular service. We do not believe that the current provision at § 460.96(a) affects an IDT's authority for determining what services are required under § 460.92, or changes the IDT's responsibility for coordinating 24 hour care delivery. However, we are concerned that the current language at § 460.96(a) is confusing and implies that there are some required services that are not covered under the PACE program because they are excluded. The term ''excluded'' implies that a service is outside of the benefit package or never covered. The term ''excluded'' could also suggest that services that are not authorized are not appealable, which runs counter to our historical

[95] *https://www.gpo.gov/fdsys/pkg/FR-1999-11-24/pdf/99-29706.pdf.*

[96] *https://www.cms.gov/Medicare/Health-Plans/pace/downloads/programagreement.pdf.*

interpretation of the PACE statutes and regulations and the policies we have promulgated to safeguard participants' right to appeal adverse decisions by the IDT. While the IDT remains responsible for determining the needs of each participant, and then implementing services that would meet those identified needs, PACE participants should always have the ability to advocate for services, through the service delivery request and appeal process, including any services the IDT determines not to be necessary (or does not authorize).

We are proposing to eliminate paragraph (b) from § 460.96 for the following reasons. Currently, this paragraph generally excludes from PACE coverage private rooms and private duty nursing services, and non-medical items for personal convenience, in an inpatient facility, but notes that a private room or private duty nursing services would be covered if medically necessary, and non-medical items for personal convenience would be covered if specifically authorized by the IDT as part of the participant's plan of care. We continue to believe that services such as a private room, private nursing services, or non-medical personal care items would not be covered under PACE, unless they were medically necessary or authorized by the IDT as part of the participant's plan of care. However, we believe that including this provision under a section of the regulation titled ''Excluded Services'' may give a false impression that the IDT would not have to consider whether those services are medically necessary or necessary to improve and maintain the participant's overall health status. As we previously indicated, the IDT is responsible for comprehensively assessing each individual participant to determine their needs, and then providing services that would meet those needs. If the IDT determines that private nursing services or a telephone are necessary to improve and maintain the participant's health status, those services would be covered for that participant under PACE. Therefore, these are not always or by definition excluded services, and we are proposing to eliminate paragraph (b) from the excluded services provision for that reason.

In addition to proposing to eliminate paragraphs (a) and (b), we are proposing to redesignate paragraphs (c) through (e) as (a) through (c).

We are not scoring this provision in the Regulatory Impact Analysis section because PACE organizations are already required to cover all PACE required services under § 460.92, and by modifying excluded services we are hoping to increase compliance with existing requirements.

3. Responsibilities of the Interdisciplinary Team

A multidisciplinary approach to care management and service delivery is a fundamental aspect of the PACE model of care (see for example, the 1999 PACE interim final rule at 64 FR 66254). The regulations at § 460.102 require in part that the IDT must comprehensively assess and meet the needs of each participant, and that the IDT members must remain alert to pertinent input about participants from team members, participants, and caregivers. While we believe many IDTs appropriately apply the multidisciplinary approach to providing care, we have learned through our monitoring efforts that some IDTs may not consider pertinent input about participants from specialists and other clinical and non-clinical staff, whether employees, or contractors (for example, home health service providers). Because these individuals have direct contact with participants, including in the participant's home, and may have a similar level of expertise as the members of the IDT listed in § 460.102(b) or expertise in another medical field, they are likely to be in the best position to provide input that may contribute to a participant's treatment plan. An IDT could not comprehensively assess a participant and provide a multidisciplinary approach to care management if it did not consider pertinent input about a participant from any individual with direct knowledge of or contact with the participant, including caregivers, employees, or contractors of the PACE organization, or a specialist. For example, if a home care aide informed the organization that a participant seems more confused than normal, the IDT might not be able to fully meet the participant's needs if it did not take this information into consideration. While the IDT is responsible for many aspects of care provided to their participants, it might not interact with their participants on a regular basis. It is important that the IDT consider input from other individuals that have more regular or direct contact with the participant population, in order to inform its ability to appropriately meet participants' needs. Therefore, we are proposing to revise § 460.102(d)(2)(ii) by adding employees, contractors, and specialists to the individuals from whom the IDT must remain alert to pertinent input. We are proposing to include specialists because there may be circumstances in which a participant is receiving care or seeking treatment options from a provider that specializes in a particular area and we believe that input from these medical professionals is vital in order for a PACE organization to provide comprehensive care to its participants. We are also proposing to add these individuals as unique sub-paragraphs under § 460.102(d)(2)(ii) in order to emphasize that these are unique groups of individuals, each of whom may provide information that is pertinent to the IDT. As part of the requirement that the IDT members remain alert to pertinent input from these individuals, we expect that the IDT members would consider all recommendations for care or services made by other team members, participants, caregivers, employees, contractors, or specialists for a participant when making treatment decisions.

We are proposing a minor change to redesignate the provisions at § 460.102(d)(1) under a new (d)(1)(i), where we are proposing to retain the current requirement that the IDT is responsible for the initial assessment, periodic reassessment, plan of care, and coordination of 24 hour care delivery. We are also proposing to add a new § 460.102(d)(1)(ii) to require the IDT to document all recommendations for care and services and, if the service is not approved, the reasons for not approving or providing that care or service in accordance with the requirements in § 460.210(b). By requiring the IDT to document all recommendations for care or services and, if not approved or provided, the rationale supporting the IDT's decisions, we believe our proposals under § 460.102(d) would better position the PACE organization and the IDT to remain alert to pertinent information and to share that information with participants, caregivers, and appeal entities when applicable.

We believe the burden associated with this provision is related to the documentation of the recommendations in the medical record. We discuss and account for the burden of documenting these recommendations in the medical record in the regulatory impact analysis.

E. Documenting and Tracking the Provision of Services Under PACE (§ 460.98)

As discussed at section VII.D. of this proposed rule, under sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act, PACE organizations provide comprehensive health care services to PACE participants in accordance with the PACE program agreement and regulations under those sections. Sections 1894(b)(1)(A) and 1934(b)(1)(A)

of the Act specify in part that PACE organizations must provide participants, at a minimum, all items and services covered under titles XVIII and XIX of the Act without any limitation or condition as to amount, duration, or scope, and all additional items and services specified in regulations, based upon those required under the PACE protocol.[97] Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act also specify that, under a PACE program agreement, a PACE organization must furnish items and services to PACE participants directly or under contract with other entities. Additionally, sections 1894(b)(1)(B) and 1934(b)(1)(B) of the Act require that a PACE organization must provide participants access to all necessary covered items and services 24 hours per day, every day of the year. These statutory provisions ensure that a PACE participant can receive all PACE covered services, as needed, 24 hours a day, every day of the year. This includes the full range of services required under the PACE statute and regulations. We have implemented these requirements in several sections of the PACE regulations. For example, we require in § 460.70 that PACE organizations must have written contracts that meet specific regulatory requirements with any outside entity furnishing administrative or care-related services not furnished directly by the PACE organization, except for emergency services as described in § 460.100. We also require PACE organizations to establish and implement a written plan to furnish care that meets the needs of each participant in all care settings 24 hours a day, every day of the year at § 460.98(a). Through oversight and monitoring, we recognized that some PACE organizations are not appropriately implementing these requirements. CMS routinely sees PACE organizations deny or restrict necessary services. PACE organizations have also documented in participants' medical records that they do not provide access to care and services 24 hours a day, regardless of participant need. CMS has also learned through monitoring of PACE organizations that some organizations are not providing all care and services through employees or contractors of the organization. Instead, these organizations purport to rely on caregivers such as family members to provide necessary care and services to participants.

We are proposing to make several modifications to § 460.98 ''Service Delivery'' in response to failure by certain PACE organizations to fulfill their responsibilities to provide all necessary care and services, through the use of employees or contractors, as expeditiously as the participant's health condition requires, and ensure access to those services 24 hours a day, every day of the year. Currently, § 460.98(a) requires that PACE organizations establish and implement a written plan to furnish the care that meets the needs of each participant in all care settings 24 hours a day, every day of the year. We are concerned that the current version of this paragraph places more emphasis on the requirement to establish a written plan than it does on the requirement that the PACE organization actually implement such a plan by furnishing services. Therefore, we are proposing to modify paragraph (a) to more clearly emphasize that PACE organizations must not only have a plan to furnish care as described in existing § 460.98(a), but must also carry it out. We propose to change the title of § 460.98(a) from ''Plan'' to ''Access to services'' in order to emphasize that the requirement is that PACE organizations provide access to services and not just have a plan. We also propose to revise the language of § 460.98(a) to emphasize that PACE organizations are responsible for providing care that meets the needs of each participant, across all care settings, 24 hours a day, every day of the year, as well as establishing a written plan to ensure that care is appropriately furnished. We believe the proposed amendments would align with the statutory requirement that PACE organizations provide access to necessary care and services at all times. We are also proposing to retain the requirement that PACE organizations must establish and implement a written plan to furnish care, with one modification to specify that the plan must ensure that care is appropriately furnished. Additionally, we want to emphasize that, both under the current regulation and the proposed amendments, the PACE organization is (and would remain, if our proposed amendments are finalized) responsible for providing this care regardless of the care setting. In other words, regardless of whether the participant receives care in the home, at the PACE center, or in an inpatient facility, the PACE organization is (and would remain) responsible for furnishing care in all care settings, 24 hours a day, every day of the year.

Currently, § 460.98(b) specifies in part that the PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long term care to each participant, and must furnish these services in at least the PACE center, the home, and inpatient facilities. We are proposing to make three changes to § 460.98(b) by modifying paragraph (b)(1) and adding new paragraphs (b)(4) and (5). Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act, and the PACE regulations at § 460.70(a), require PACE organizations to furnish administrative and care-related services by employees or contractors of the organization. Through monitoring and oversight we have identified instances where PACE organizations have relied on individuals other than employees or contractors to provide necessary care and services to participants. To address these concerns we are proposing to add a reference to § 460.70(a) at § 460.98(b)(1) to reiterate the requirement that PACE organizations furnish all services through employees or contractors, regardless of whether the services relate to medical, health, or social services, including both acute and long term care.

We are also proposing to add a new paragraph at § 460.98(b)(4), to require that all services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's overall medical, physical, emotional and social needs. While there is a similar requirement in § 460.104(e)(4), that services that result in a change to the care plan must be provided as expeditiously as the participant's health condition requires, we have identified through monitoring and oversight that participants routinely receive care that is determined necessary but is not formally incorporated into the care plan, and is instead handled through discipline-specific progress notes or treatment plans. For example, the primary care provider may order pain medication for a participant, but not incorporate that order into the participant's plan of care. Regardless of whether the service is in the plan of care, we believe that the PACE organization retains the responsibility of ensuring that participants receive all recommended or ordered treatment or care as expeditiously as the participant requires. We are proposing to specify at § 460.98(b)(4) that services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs. We do not believe that we could implement a specific timeframe given the vast array of services that PACE organizations provide. Additionally, determining how quickly a service must

[97] The original PACE protocol was replaced by the PACE program agreement (84 FR 25613).

be provided would depend on more than just the physical health of the participant, and PACE organizations should consider all aspects of the participant's condition, including their social, emotional, and medical needs, when determining the provision of services. For example, if the participant has a high risk of falling, the provision of a service that mitigates that risk may be necessary within a very short window of time. However, if the necessary service is a preventative trip to the dentist for routine care, the provision of that service may not be as urgent. These decisions must be made on a case by case basis and the PACE organization will be expected to demonstrate that services were provided as expeditiously as the participant's medical, physical, emotional, and social needs require through monitoring efforts by CMS.

Lastly, we are proposing adding a new paragraph (b)(5) to § 460.98 to require PACE organizations to document, track, and monitor the provision of services across all care settings, regardless of whether services are formally incorporated into the participant's plan of care. We are proposing that PACE organizations would be required to document, track and monitor necessary services in order to ensure that they are actually provided in accordance with § 460.98(b)(4). CMS' audits have revealed that in practice, certain PACE organizations do not routinely track the services provided and often lack documentation that services have been rendered. In order for the IDT to remain alert to pertinent information and coordinate care appropriately, we believe the PACE organization must be capable of ensuring that all approved services are tracked and documented, regardless of whether they are formally incorporated into the participant's plan of care. This means that not only should a PACE organization document that a service has been ordered, but that the PACE organization should also document when and how the approved service was provided. We believe that monitoring the provision of services is vital for a PACE organization in order to ensure their participants are receiving appropriate services, and that those services are achieving the desired effect. In addition, CMS regulations at § 460.134 require that PACE organizations use objective measures to demonstrate improvement across a range of areas, such as the utilization of PACE services and the effectiveness and safety of staff-provided and contracted services, including the promptness of service delivery, among other requirements. We believe that this proposal will ensure that PACE organizations are able to more effectively meet the minimum requirements established at § 460.134.

F. Documentation in Medical Records Under PACE (§ 460.210)

In accordance with § 460.210(a), a PACE organization must maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards, that is accurately documented and available to all staff, among other requirements. We have previously discussed the importance of maintaining a complete record for each participant. In the preamble to the 2006 PACE final rule, we stated that, because care for the PACE population will be provided by a variety of sources (for example, PACE center employees, contracted personnel, hospital staff, nursing home staff, etc.), it is critical that all information on the participant be documented in the medical record to ensure quality and continuity of care. 71 FR 71326. CMS currently specifies at § 460.210(b) the minimum required contents of a medical record. Based on audit and oversight experience, we have identified additional requirements that we believe should be added under § 460.210(b) to ensure that participant medical records are fully comprehensive.

We are proposing to redesignate § 460.210(b)(4) through (12) as (7) through (15), and to add three new paragraphs under § 460.210(b) to address how recommendations for care and treatment, decisions regarding those recommendations, and communications relating to a participant's care, health or safety should be documented in the medical record. Specifically, we are proposing to add a new paragraph (b)(4) that would require the PACE organization to document all recommendations for services made by employees and contractors of the PACE organization, including by all specialists such as dentists, neurologists, cardiologists, and others, in the participant's medical record. We believe that all recommendations for services from these sources must be documented in order for the IDT to remain alert to all pertinent information, even if the IDT decides not to pursue the recommendations, for example based on a determination that the service is not necessary. Recommendations are made based on the employee or contractor's determination that a participant might benefit from a particular service given the participant's health status or condition. Even if the IDT ultimately decides that the recommended service would not be necessary to improve and maintain the participant's health status, the IDT should document that recommendation in order to remain alert to why a particular contractor or employee believed that service was necessary as required by § 460.102(d)(2)(ii).

Additionally, we are proposing to add a new paragraph (b)(5) that would require the IDT to document in the medical record the reason(s) for not approving or providing a service recommended by one of these sources. When an employee, contractor, or specialist recommends a service within the scope of their authority to practice, we believe that it is necessary for the IDT to consider this information and document any decision against providing the recommended service in the medical record. For example, if a gastroenterologist recommends that a participant receive drug therapy for Hepatitis C, and after reviewing the recommendation the IDT determines that treatment is not medically necessary or is contraindicated, we are proposing to require the IDT to document in the participant's medical record the rationale for not providing the recommended drug therapy, including the clinical criteria used as the basis for that determination. This would not only ensure that the IDT can review the information used to make the decision, but also that the participant has access to information about the basis of the decision not to provide a recommended service. This proposal would also align with the requirement we finalized in the 2019 PACE final rule that requires the IDT to document the rationale for determining certain services are not necessary in the participant's plan of care following the initial comprehensive assessment. 84 FR 25643. While the 2019 PACE final rule required the IDT to follow this process during the development of the initial care plan, we are expanding the requirement to account for situations that arise after the initial plan of care is developed. For example, a participant may be diagnosed with diabetes after the development of the initial care plan, and should the PACE organization determine that treatment is not necessary, we would expect that it document that decision and the reasons for that decision in the participant's medical record.

We are also proposing to require PACE organizations to maintain certain written communications received by the PACE organization in the participant's medical record. The PACE program presents unique challenges in terms of providing care to participants. PACE

participants require a nursing facility level of care and often have complex medical needs. When a Medicare or Medicaid beneficiary is in a nursing home, they have daily interactions with staff, and their needs, including changes in condition, are noted by the staff and acted upon. PACE participants, on the other hand, largely remain in their own homes and might not be seen on a daily basis by PACE organization staff. PACE participants do, however, often have regular interactions with caregivers, family members, neighbors, and other members of their communities, as well as with social service organizations like a local Area Agency on Aging (AAA) or Adult Protective Services (APS) agency. We believe that maintaining a comprehensive, complete, and accurate medical record allows a PACE organization to remain alert to all information that is relevant to a participant's care, health, or safety and to provide appropriate and timely care to the participant. We also believe information about a participant's care, health, or safety provided to a PACE organization by any of the sources previously noted could be a critical part of providing comprehensive care to the participant. We are therefore proposing to add a new paragraph (b)(6) to § 460.210, to require PACE organizations to maintain in a participant's medical record original documentation of any written communication relating to the care, health, or safety of a participant that the PACE organization receives from certain sources in any format (for example, emails, faxes, letters, etc.). At a minimum, PACE organizations would be required to maintain communications from the participant, his or her designated representative, family members, caregivers, or any other individual who provides information pertinent to a participant's care, health or safety, as well as communications from advocacy or governmental agencies like an AAA or APS. As we indicated in the discussion regarding § 460.200 at section VII.C. of this proposed rule, we are also requiring that the PACE organization maintain this information in its original written form rather than summarizing the information in the participant's record.

G. PACE Participant Rights: Contact Information and Access Requirements (§ 460.112)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify in part that PACE organizations must have in effect written safeguards of the rights of enrolled participants including a patient bill of rights. Previously, we established in § 460.112 certain rights to which a participant is entitled. This includes the participant's right to receive accurate, easily understood information and to receive assistance in making informed health care decisions under § 460.112(b); and the participant's right to a choice of health care providers, within the PACE organizations network, that is sufficient to ensure access to appropriate high-quality health care under § 460.112(c). CMS is proposing to add three new participant rights in § 460.112 to increase beneficiary protections: The right to contact 1–800–MEDICARE for information or to make a complaint; the right to have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines; and the right to receive necessary care across all care settings, up to and including placement in a long term care facility when the PACE organization can no longer maintain the participant safely in the community through the support of PACE services.

Section 1804(b) of the Act requires CMS to provide information on Medicare programs through 1–800–MEDICARE, as a means by which individuals may seek information and assistance for Medicare programs. This number may be utilized by Medicare beneficiaries to address coverage questions, find plan information, or make complaints related to the Medicare program. While PACE organizations are responsible for providing to all participants all services covered under Medicare and Medicaid, including prescription drugs, and other services determined necessary by the IDT to improve and maintain the participant's overall health status, PACE organizations are not required to provide this toll-free number to participants in any current communication. In the MA program, MA organizations must provide this information to beneficiaries in their Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) under § 422.111 as well as longstanding guidance under the Medicare Communications and Marketing Guidelines.[98] We have discovered through oversight and monitoring efforts that PACE participants and/or their caregivers are often not aware that, in addition to the internal grievance process under § 460.120, participants also have the right to contact 1–800–MEDICARE; for example, to file quality of care complaints, including filing a complaint regarding the delivery of a necessary service. For example, if the IDT approved treatment for a specific condition, but the participant never received that treatment, the participant or caregiver could call 1–800–Medicare to lodge a complaint. Given the frailty of the PACE population, we believe it is important that these participants be explicitly notified of their right to have their complaints heard and resolved by calling 1–800–MEDICARE. When a participant files a complaint with 1–800–MEDICARE, the complaint gets logged and routed to a CMS account manager or case worker in order to ensure it is appropriately responded to and resolved. To ensure PACE participants are notified about 1–800–MEDICARE, we are proposing to amend § 460.112 by adding a new paragraph (b)(4) which would specify that participants have the right to contact 1–800–MEDICARE for information and assistance, including to make a complaint related to quality of care or delivery of a service. PACE organizations are required under § 460.116(c)(2) to display the PACE participant rights in a prominent location in the PACE center, and to include the participant bill of rights in the enrollment agreement under § 460.154(m). Thus, we believe adding (b)(4) would ensure each PACE organization makes the 1–800–MEDICARE number available to participants by posting it in an accessible location at the PACE center and including it in the enrollment agreement.

We also propose to include a participant's right to have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines at new § 460.112(c)(3). PACE organizations are responsible for ensuring participants receive all necessary care from specialists, which is coordinated through the primary care provider and IDT in accordance with § 460.102(c)(2)(ii) and (d)(1). In addition, as noted in the preamble to the 1999 PACE interim final rule that implemented the PACE program (see 64 FR 66260) and the preamble to the 2006 PACE final rule that implemented § 460.92 of the regulations (see 71 FR 71305), PACE organizations must utilize clinical practice guidelines to ensure the quality of care for PACE participants. CMS has also historically required the use of clinical practice guidelines and professional standards in determining outcome measures applicable to the care

[98] *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial.html.*

of PACE participants as part of the PACE organizations quality improvement program (see § 460.134(b)). The 1999 PACE interim final rule also established the expectation that PACE organizations will utilize current clinical standards as a routine part of their daily operations. 64 FR 66260. Because part of the purpose of the quality improvement program is to identify areas to improve or maintain the delivery of services and patient care, CMS believes that these same guidelines and standards should be used as part of care planning and in making determinations about services as discussed in section VII.D. of this proposed rule. However, CMS' audits of PACE organizations have shown that some PACE participants have not received timely access to appropriate specialists as necessary to improve and maintain the participant's overall health status and in accordance with current clinical practice guidelines. Instead, the IDTs at some PACE organizations seem to be making their decisions based on factors not related to the participant's health condition. In some instances, participants have experienced negative outcomes because they have not received access to a specialist. Therefore, we propose to redesignate paragraph (c)(3) as (c)(5) and add a new paragraph (c)(3), which expressly states each participant has the right to reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines.

Lastly, we are proposing to add a new paragraph at § 460.112(c)(4) to address a participant's right to receive care across all care settings. A PACE organization is expected to provide for the care that is necessary for each participant and determine the appropriate setting in which to provide that care, up to and including placement in a long term care facility when a participant's condition requires it (see § 460.98(a) and (b)). However, CMS' monitoring and audit activity show that some PACE organizations are not providing long-term care services, even when their IDTs determine a participant can no longer live safely in their home and requires a higher level of care. We have learned that in some cases, affected participants disenroll from PACE in order to receive the long-term care that is needed. One of the purposes of the PACE program is to enable frail, older adults to live in the community as long as medically and socially feasible (see § 460.4(b)(3)). PACE organizations are also responsible for furnishing comprehensive medical, health, and social services that integrate acute and long-term care, and providing services that are accessible and adequate to meet the needs of its participants. (See § 460.98(b) and (d)(2) respectively). Lastly, enrollment in the PACE program continues until the participant's death, regardless of changes in health status, unless the participant voluntarily disenrolls, or is involuntarily disenrolled. (See § 460.160(a)). A PACE organization cannot deny placement in a long-term care facility if the IDT determines the participant requires 24 hour care but the PACE organization does not have a method for providing that care in the home through either its employees or contractors. See the relevant discussion under section VII.E. of this proposed rule regarding providing participants access to services 24 hours a day, every day of the year, across all care settings. In order to provide more specific detail about what this fundamental program requirement entails, we are proposing to add § 460.112(c)(4) which would state that a participant has the right to receive necessary care in all care settings up to and including placement in a long term care facility when the PACE organization can no longer provide the services necessary to maintain the participant safely in the community.

H. Enforcement Action Appeal Rights Under PACE (§ 460.56)

Sections 1894(e)(7) and 1934(e)(7) of the Act specify that, under regulations, the provisions at section 1857(h) of the Act, governing the procedures for termination of a contract with an MA organization, apply to the termination and sanctions of a PACE program agreement and PACE organization in the same manner as they apply to an MA organization under Medicare Advantage. The current enforcement provisions at 42 CFR part 460, subpart D, do not specify a process for appeals related to civil money penalties or intermediate sanctions. However, at § 460.54, the regulations include appeal rights for termination procedures. In the preamble to the 1999 PACE interim final rule, we discuss the requirement in the BBA of 1997 that we take into account some of the requirements established for MA as we develop regulations for PACE organizations in certain areas common to both programs, such as beneficiary protections, payment rates, and sanctions. 64 FR 66236. CMS has interpreted this legal framework as granting the agency the authority to utilize the appeals processes that apply to MA organizations under § 422.756 when imposing a suspension of enrollment or payment, or imposing civil money penalties on PACE organizations. Although it has not been codified in regulation, CMS currently provides PACE organizations with these appeal rights when imposing enforcement actions under §§ 460.42, 460.46, and 460.48(b).

Therefore, in an effort to enhance transparency and ensure that PACE organizations are aware of their right to appeal an enforcement action, we are proposing to add a new § 460.56 in subpart D of the PACE regulations to affirmatively state that a PACE organization may request a hearing according to the procedures at § 422.756 when CMS imposes a sanction or civil money penalty under § 460.42, § 460.46, or § 460.48(b) on PACE organizations.

For suspensions of enrollment or payment listed under §§ 460.42 and 460.48(b), CMS will follow the hearing procedures for imposing intermediate sanctions at § 422.756(b), which includes the right to a hearing before a CMS designated hearing officer under subpart N of part 422. Under the process specified at § 422.756(b), CMS provides organizations with a notice of intent to impose sanctions and their right to a hearing before a CMS hearing officer. Organizations are given 15 days from the date of the notice to request a hearing.

For civil money penalties listed under § 460.46, CMS will follow the procedures for imposition of civil money penalties at § 422.756(e)(2)(v), which includes the right to a hearing before an Administrative Law Judge (ALJ) under subpart T of part 422. In addition, CMS must send a written notice of the agency's decision to impose a civil money penalty, the amount of the penalty, the date the penalty is due, information about the organization's right to a hearing and where to file the request for hearing.

We believe this proposal will ensure PACE organizations understand the process CMS utilizes for imposing these enforcement actions, as well as the PACE organization's right to appeal those actions.

We have not included § 460.48(a) or (c) in the proposed regulation because those provisions refer to the termination of a PACE program agreement, for which procedures are already set forth at § 460.54. However, § 460.48(b) authorizes CMS to withhold payment under the PACE program agreement, which is similar to the suspension of payment provided at § 460.42(b)(1). Therefore, the procedures at § 422.756 would apply, as we are proposing to specify at § 460.56(a).

I. PACE Definitions (§ 460.6)

As discussed briefly at section VII.A. of this proposed rule, we are proposing to modify our existing definition of ''services.'' Currently, the term ''services'' is defined as including items and services. We are proposing a change to use the term ''service'' in § 460.6 to be consistent with the use of the singular in the terms defined under § 460.6. The definition of the singular ''service'' would also apply to the plural ''services.'' In addition, we are proposing to modify our definition of ''service'' to better reflect the full scope of the PACE benefit package by stating that the term ''service'', as used in part 460, means all services that could be required under § 460.92, including items and drugs. In the 1999 PACE interim final rule, we stated that required services included all current Medicare services, all Medicaid-covered services as specified by the state's approved Medicaid plan, and specifically included ''drugs and biologicals'' as a part of a list of minimum benefits PACE organizations were required to provide. (64 FR 66246 and 66301). In the 2006 PACE final rule, we removed the specific listing of all required services because we determined that it was not possible to provide a complete list of all services that must be furnished to participants if ordered by the IDT. (71 FR 71281). Instead, we adopted the language that is currently used in § 460.92 to identify the services required as a part of the PACE benefit package. Since that time, through CMS' monitoring and oversight, we have found that some PACE organizations do not realize that they are responsible for providing the full Medicare benefit, including the provision of Part D drugs. Therefore, we are proposing to make changes by adding ''drugs'' to the definition of services for PACE purposes which is consistent with how we have historically defined the types of services that are required in PACE. We believe this change is necessary to remove potential ambiguity about the meaning of the terms ''service'' or ''services'' when used in the PACE regulations.

VIII. Technical Changes

A. Exclusion of Services Furnished Under a Private Contract (§ 422.220)

CMS proposes to update regulations that pertain to private contracts in order to provide greater clarity as to how such provisions should apply. Currently, section 1802(b)(6)(B) of the Act defines ''physician,'' in respect to private contracts, as a term that is defined by paragraphs (1), (2), (3), and (4) of section 1861(r) of the Act; however, § 422.220 currently defines ''physician,'' in respect to private contracts, using only paragraph (1) of section 1861(r) of the Act—narrowing the regulatory definition to exclude physicians who are not doctors of medicine or osteopathy. To avoid confusion about what kinds of providers the opt-out and private contracting rules apply to, we propose to extend the regulatory definition of ''physician'' to match the statutory definition when the term is used in regard to private contracts. CMS proposes to achieve this by adding references to paragraphs (2), (3) and (4) of section 1861(r) of the Act to the definition of ''physician'' at § 422.220 to make the regulatory provision consistent with the statute.

In addition, CMS proposes to clarify the prohibition at § 422.220 in regard to the types of items and services an opt-out provider may and may not receive payment for from an MA organization. Section 4507 of the BBA of 1997 amended section 1802 of the Act to allow private contracts for Part B services when, among other things, a physician or practitioner (as those terms are defined in section 1802(b)(6)) of the Act signs an affidavit that states the physician or practitioner will not submit any claim for a Medicare-covered item or service except in specified cases of emergency or urgent care, and a copy of the affidavit is filed with the Secretary. When a physician or practitioner chooses to file a signed affidavit as described in section 1802(b) of the Act and enters into a private contract with a Medicare beneficiary for services covered under Part B, the physician or practitioner is considered by CMS to be ''opted out.'' Section 1802 of the Act permits private contracts for Part B services under specific conditions when a physician or practitioner agrees to forego Medicare payment for benefits under Title XVIII, among other requirements (for example, related to information provided to the beneficiary) that are not specifically relevant here. As relevant to the MA program, section 1802(b)(1)(B)(ii) states that an opt-out physician or practitioner must receive ''no amount for such item or service from an organization which receives reimbursement for such item or service under this title directly or on a capitated basis.'' The Medicare statute, specifically sections 1853 and 1854 of the Act, provide for *capitation payments* to MA organizations for items and services that are covered under Parts A and B (excluding hospice; beginning January 1, 2021, kidney acquisition costs for kidney transplants; and when there is a national coverage determination or legislative change in Medicare benefits). We believe that payments for supplemental benefits are outside the scope of the statutory restriction on payments to opt-out providers. This is also consistent with how § 405.455 limits the consequences of the opt-out to ''Medicare covered services,'' which means items, services and drugs covered by Part A, Part B or Part D. Section 40.19, Chapter 15 of the Medicare Benefit Policy Manual reiterates that the rules for private contracts do not pertain to items and services ''categorically not covered'' under Medicare. Further, in the final rule published June 29, 2000 (65 FR 40170) that adopted § 422.220, we explained that a Medigap policy may cover—and pay—for items and services furnished by an opted-out provider when the benefits are not covered by Medicare regardless of the opt-out. (65 FR 40262). By amending § 422.220 to exclude supplemental benefits—which may only be benefits that are not otherwise covered by Medicare—from the prohibition on payment to opted-out providers, we would be bringing the MA regulation into alignment with the policy in the FFS program.

Thus, CMS proposes amending § 422.220 to clarify that the restrictions on payments to opt-out providers apply only to payments for basic benefits (that is, items and services covered under Parts A and B). As the term ''basic benefits'' is defined in § 422.100(c) and used throughout Part 422 regulations governing the MA program to refer to these Medicare benefits, we use that term here and in our proposed amendments to § 422.220. We also propose to specify in these amendments that MA organizations may make payments to opt-out providers for supplemental benefits.

To ensure that the regulation is clear, we are also proposing some restructuring of the regulation so that paragraph (a) states the prohibition on payment while paragraphs (b) and (c) direct when an MA organization must or may nonetheless pay an opt-out provider. As proposed, paragraph (a) largely parrots the existing regulation text but limits the prohibition on payment to basic benefits and has new text to explain how paragraphs (b) and (c) are the exceptions to the prohibition. We propose to designate the last sentence of the current regulation, which requires an MA organization to pay for emergency or urgently needed services furnished by an opted-out physician or practitioner who has not signed a private contract with the beneficiary, as paragraph (b); our

proposal includes some minor technical revisions to the sentence. We also propose a new paragraph (c) to state that an MA organization may make payment to an opted-out physician or practitioner that are not basic benefits, but are provided to a beneficiary as a supplemental benefit. We use the terms ''basic benefits'' and ''supplemental benefits'' in our proposal consistent with how those terms are used in §§ 422.100(c) and 422.102 and with our proposals in sections II.A. and VI.F. of this proposed rule.

B. Disclosure Requirements (§ 422.111)

On April 15, 2011, CMS amended § 422.111(b)(12) to state that CMS may require an MA organization to furnish directly to enrollees, in a manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under Part 422. While the text of paragraph (b)(12) accurately reflects the intent of the proposal, its placement is inconsistent with the type of information paragraph (b) requires for disclosure; paragraph (b) pertains to generalized information about a plan, and generally specifies what information must be included in a plan description that is provided on an annual basis. The claims information that must be disclosed under paragraph (b)(12) is specific and unique to an individual enrollee and does not describe the plan's design and benefits. Therefore, we do not believe it is appropriate to list this notice as part of § 422.111(b) and are proposing to redesignate this requirement to paragraph (k) with changes to codify existing guidance on the scope and content of the EOB. Under our proposal, the substance of current paragraph (b)(12) is moved to paragraph (k), with a minor change to delete the phrase ''CMS may require'' and to add the word ''must'' after ''MA organization'' to clarify that the notices are required.

Currently, MA organizations are required to disclose claims data such as the amount a provider billed a plan and the corresponding billing code(s) used, the total cost approved by the plan, the plan's share of the total cost, and the enrollee's share of total cost. MA organizations are required to disclose specific claims data to their enrollees on a monthly or quarterly cycle, in an EOB. The MA organization must include all Part C claims processed during the reporting period, including all claims for Part A and Part B covered items and services, mandatory supplemental benefits, and optional supplemental benefits. CMS proposes to codify these existing requirements at § 422.111(k)(1), including that the disclosed data include the following for each claim: Descriptor, billing code and amount billed; total cost approved for reimbursement; share of the total cost paid by the plan; and the share of the total cost for which the enrollee is liable.

In addition, the current guidance provides that the claims data elements must include year-to-date information. For each reporting period, EOBs must contain cumulative, year-to-date totals for the amount providers have billed the plan, the total costs that have been approved by the plan, the plan's share of the total costs, and the enrollee's share of the total costs. We are proposing to codify this guidance in paragraph (k)(2) by requiring the EOB to include specific year-to-date totals as follows: (i) The cumulative amount billed by all providers; (ii) The cumulative total costs approved by the plan; (iii) The cumulative share of total cost paid for by the plan; (iv) The cumulative share of total cost for which the enrollee is liable; (v) The amount an enrollee has incurred toward the MOOP limit, as applicable; and (vi) The amount an enrollee has incurred toward the deductible, as applicable.

In addition to EOB claims data elements, we are also proposing to codify existing requirements concerning additional information at § 422.111(k)(3). Currently, an MA organization must also include in the EOB (i) clear contact information for enrollee customer service; (ii) instructions on how to report fraud; and (iii) for any EOB that includes 1 or more denied claims, the EOB must include, in the same correspondence, a clear identification of the claim(s) denied as well as information about the denial and the enrollee's appeal rights. We note that the requirement to inform an enrollee of a claims denial at the time the EOB is issued is not a substitute for the denial notices required under the appeal regulations in subpart M.

CMS also proposes to codify the existing issuance cycles for which an MA organization must send EOBs. Currently, MA organizations choose to either send EOBs on a monthly basis or quarterly basis with per-claim notification. MA organizations that send EOBs monthly must send them before the end of each month that follows the month a claim was filed. For example, an MA organization must send a monthly EOB for a claim filed on June 1, 2019 no later than July 31, 2019. A per-claim notice must be sent on the same cycle as a monthly EOB, which is before the end of each month that follows the month a claim was filed; MA organizations that choose to send per-claim notices must also send quarterly summary EOBs. MA organizations that choose to send EOBs on a quarterly basis must send an EOB no later than the end of each month following the quarter a claim was filed. A per-claim notice is not a substitute for the quarterly EOB. CMS proposes to codify these existing requirements at paragraph (k)(4).

C. Special Requirements During a Disaster or Emergency (§ 422.100)

Section 422.100(m)(5)(iii) currently states, ''Provide the information described in paragraphs (m)(1), (2), (3), and (4)(i) of this section on its website.'' However, § 422.100(m) does not have a paragraph (m)(4)(i). In the Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs proposed rule (79 FR 1918) and the Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs final rule (80 FR 7912), we explained that this requirement was to post the disaster and emergency policies in order to facilitate enrollee access to needed services while normal care delivery is unavailable, which would enable enrollees and providers to know the payment policies for out-of-network services provided during disasters. Paragraph (m)(5)(i) describes the terms and conditions of payment during the public health emergency or disaster for non-contracted providers furnishing benefits to plan enrollees residing in the state-of-disaster area, and is clearly the information we intended to be posted by the MA organization. Therefore, we are proposing to amend § 422.100(m)(5)(iii) to correct the cross-reference from paragraph (m)(4)(i) to paragraph (m)(5)(i). In addition, the regulation text uses the term ''website'' but the non-hyphenated non-capitalized term ''website'' is now commonly used and more consistent with other regulations in part 422. We are proposing to update the regulation text to use ''website'' as well.

D. Effective Date for Exclusion of Coverage for Kidney Acquisitions From Basic Benefits (§ 422.100)

Section 1852(a)(1)(B)(i) of the Act defines the term ''benefits under the original Medicare Fee-for-Service program option'' for purposes of the requirement in subparagraph (a)(1)(A) that each MA organization provide enrollees such benefits. Section 17006(c)(1) of the Cures Act amended

section 1852(a)(1)(B)(i) of the Act by inserting ''or coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d)'' after ''hospice care.'' Per section 17006(c)(3) of the Cures Act, this amendment applies with respect to plan years beginning on or after January 1, 2021. Thus, effective January 1, 2021, MA plans will no longer cover organ acquisitions for kidney transplants.

In the April 2019 final rule, we amended the definition of ''basic benefits'' at § 422.100(c)(1) to include ''additional telehealth benefits,'' and in doing so, we also amended § 422.100(c)(1) to note the new exclusion of coverage for organ acquisitions for kidney transplants (in addition to the existing exclusion for hospice care). However, we inadvertently omitted the identification of the 2021 effective date for this change set forth in the Cures Act.

We are proposing a technical correction that would add the 2021 effective date to § 422.100(c)(1) for the exclusion of original Medicare coverage for organ acquisitions for kidney transplants. Specifically, we propose to correct the phrase ''(other than hospice care or coverage for organ acquisitions for kidney transplants)'' to read: ''(other than hospice care or, beginning in 2021, coverage for organ acquisitions for kidney transplants).'' This provision is technical and is therefore not expected to have economic impact beyond current operating expenses.

E. Add Back Cost Plan Related Sections From Previous Final Regulation (§ 422.503)

In the Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Final Rule (hereinafter referred to as the May 2014 final rule), we finalized regulations affecting the cost plan non-renewal-related requirements (79 FR 29959). The final regulation inadvertently identified the non-renewal section as § 422.503(b)(4)(vi)(G)(*5*)(*i*) and (*ii*) when instead the revisions should have been specified as revising § 422.503(b)(5)(i) and (ii). Although the regulatory text for the provision was published in the May 2014 final rule, it was not correctly codified in the CFR. In this rule, we propose to designate the provision in the correct paragraph of § 422.503. For additional discussion of this provision, including public comments on the proposal, see the May 2014 final rule.

This section provides that an entity seeking to offer an MA organization may not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan. We are proposing to codify a policy adopted in the May 2014 final rule (79 FR 29850 through 29851 and 29959). In new § 422.503(b)(5)(i), we specify that an entity seeking to contract as an MA organization must not accept, or share a corporate parent organization owning a controlling interest in an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan. In new § 422.503(b)(5)(ii), we specify that an entity seeking to offer an MA organization must not accept, or be either the parent organization owning a controlling interest of or subsidiary of, an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan. We are also proposing minor technical corrections to the regulation text described in the May 2014 final rule to improve the flow of the regulation text.

F. Definition of ''Institutionalized'' for Institutional Special Needs Plans (I–SNPs) (§ 422.2)

Section 1859(b)(6)(B)(i) of the Act permits the Secretary to define the term ''institutionalized'' for the purposes of establishing eligibility criteria for Medicare Advantage (MA) special needs plans for individuals who are institutionalized (I–SNPs). In addition, section 1851(e)(2)(D) of the Act permits the Secretary to define the term for purposes of eligibility for a continuous open enrollment person to enroll or change enrollment in an MA plan, except for MA MSA plans. As currently defined in § 422.2, ''institutionalized'' means an MA eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in a long-term care (LTC) facility which is a skilled nursing facility (SNF) nursing facility (NF); SNF/NF; an intermediate care facility for individuals with intellectual disabilities (ICF/IID); or an inpatient psychiatric facility. CMS codified this definition of institutionalized at § 422.2 in the January 2005 final rule) (70 FR 4588). In combination with the definition of ''special needs individual'' (also in § 422.2) and the eligibility requirements in § 422.52, this definition restricts enrollment by MA eligible individuals into I–SNPs, which are one of three specific coordinated care plans (CCPs) for special needs individuals authorized by section 1859 of the Act. CMS also uses this definition to establish a special election period (SEP) for institutionalized individuals. Under § 422.62(a)(4), an individual who is eligible to elect an MA plan and who is institutionalized, as defined in § 422.2, is not limited, except as provided in § 422.62(d) for MA MSA plans, in the number of enrollment elections or changes the individual may make.

As currently defined under § 422.2, the definition of institutionalized is limited in scope, given the array of institution types that exist today. We are proposing to revise the current regulatory definition of the term for purposes of defining a special needs individual and eligibility for the continuous open enrollment period to take into account current guidance and to provide additional flexibility to account for changes in the types of institutions that could potentially be used for I–SNPs that are not covered by the current definition of institutionalized. The current sub-regulatory definition for an institutionalized individual is broader than the regulatory definition and includes three additional institution types, which has led to some confusion among MA organizations seeking to offer I–SNPs. We are proposing to expand the definition of ''institutionalized'' in § 422.2 to reflect the evolution of institutions over time and the current landscape of institutional health care today. We are proposing to amend the definition of institutionalized, as defined in § 422.2, to incorporate additional types of long-stay institutions. Our proposed change would align the regulatory text with existing operational practice and current guidance, clarify our policy for MA organizations, and promote the expansion of I–SNP offerings under the MA program.

The current definition of institutionalized in § 422.2 is based on a list of five institutional settings. While chapter 16b of the Medicare Managed Care Manual (MMCM) also lists the same five types of institutions, it also refers to the MA Enrollment and Disenrollment Guidance, which lists seven institutional categories. The list in the MA Enrollment and Disenrollment Guidance is based on institutions that are identified in some way in Titles XVIII or XIX of the Act in connection with the Medicare and Medicaid programs. As defined in the MA Enrollment and Disenrollment Guidance, an institutionalized individual is an individual who resides in an institution of the following settings:

- SNF as defined in section 1819(a) of the Act;
- NF as defined in section 1919(a) of the Act;

• Intermediate care facility for the mentally retarded (ICF/MR) as defined in section 1905(d) of the Act (now generally referred to as an intermediate care facility for the intellectually and developmentally disabled);
• Psychiatric hospital as defined in section 1861(f) of the Act;
• Rehabilitation hospital or unit as defined in section 1886(d)(1)(B) of the Act;
• LTC hospital as defined in section 1886(d)(1)(B) of the Act; or
• Hospital which has an agreement under section 1883 of the Act (a swing-bed hospital). We propose to codify this list of seven institutions in the definition of institutionalized such that an individual who continuously resides in or is expected to continuously reside in one of these institutions for 90 days or longer meets the definition.

We are also proposing to create criteria that would accommodate changes in forms of institutional care within American healthcare without sacrificing regulatory and statutory provisions surrounding I–SNPs. Specifically, we are proposing that the definition of institutionalized include, subject to CMS approval, an additional facility that is not listed previously but (i) furnishes similar long-term, healthcare services that are covered under Medicare Part A or Part B or Medicaid and (ii) whose residents have similar needs and healthcare status as residents of one or more facilities previously listed. Therefore, under this proposal, CMS could permit an MA organization to offer an I–SNP to serve beneficiaries that continuously reside in facilities that meet this new standard but are not listed in the definition, provided the plan meets the remaining criteria for I–SNPs.

We are proposing to amend the definition of institutionalized at § 422.2 to incorporate the list of institutions from the MA Enrollment and Disenrollment Guidance and to adopt a standard for the identification of additional institutions. We believe these proposed changes will provide greater clarity in terms of institutional status and beneficiary eligibility to enroll in an I–SNP. The current regulatory definition of institutionalized lacks critical statutory criteria establishing I–SNP enrollment qualifications and institutional status. In addition, our proposal broadens the definition of institutionalized to include rehabilitation hospitals, LTC hospitals, and swing-bed hospitals. The extension of the definition to these other institution types will increase enrollee choice regarding MA plan options that deliver specialized services to residents of qualifying institutions. Further, making the special enrollment period described in § 422.62(a)(4) available to residents of these facilities reduces confusion among stakeholders and eligible beneficiaries by aligning the SEP and I–SNP eligibility policies.

We seek comment on our proposed amendment to the definition of institutionalized at § 422.2 and specifically on the expansion of the definition to include rehabilitation hospitals, LTC hospitals, swing-bed hospitals, and for other institutions meeting the proposed standard. We also solicit comment on whether our proposed standard should use additional criteria. We acknowledge that this proposed definition does not align with § 423.772, which defines ''institutionalized individual'' as a full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month, as defined under section 1902(q)(1)(B) of the Act. When we published the January 2005 final rule, we noted that provision was an income and resource-based definition for the purpose of determining Part D premiums and cost sharing subsidies for low-income individuals. The term ''institutionalized'' as defined in § 422.4 is used for purposes of identifying a vulnerable population of individuals who reside in certain institutions and might benefit from enrollment into an I–SNP. In proposing a redefinition of ''institutionalized'' at § 422.2, we continue our position that § 423.772 serves a different purpose, unrelated to defining an institutionalized special needs individual who is eligible for I–SNP enrollment or for the special enrollment period for such individuals. We believe that the most immediate impact of this definitional change will be on I–SNP options, and that this change will help provide further clarity for stakeholders regarding the applicability of the definition as part of the criteria for establishing I–SNP beneficiary eligibility as it pertains to the authority under section 1859(b)(6)(B)(i) of the Act.

In addition to institution-based enrollment, I–SNPs may also enroll MA eligible individuals living in the community, but requiring an institutional level of care. These types of I–SNPs are known as Institutional Equivalent SNPs. When an I–SNP opts to enroll individuals prior to having at least 90 days of institutional level care, a CMS-approved needs assessment must be conducted. Results of the assessment must demonstrate that the individual's condition makes it likely that either the length of stay or the need for an institutional level of care will be at least 90 days. We are not proposing to amend the definition of ''institutionalized-equivalent'' in § 422.2 because it is not impacted the by our proposed amendment to the definition of ''institutionalized'' under § 422.2.

We are not scoring this provision in the Regulatory Impact Analysis section because it codifies and reconciles existing guidance and practice for the uses of the term ''institutionalized'' in part 422. We believe that there is no impact on stakeholders following the current guidance. We are also not scoring this provision in the Collection of Information section since we believe all information impacts of this provision have already been accounted for under OMB control number 0938–1296 (CMS–10565), but seek comment on this assumption.

We seek comment on the proposed amendment to the definition of institutionalized under § 422.2 and the potential impact the proposal would have on MA organizations offering I–SNPs, enrollees, and providers.

G. Medicare Electronic Complaint Form (§§ 422.504 and 423.505)

On April 15, 2011, CMS amended §§ 422.504 and 423.505 to add a new §§ 422.504(a)(15) and 423.505(b)(22) requiring MA and Part D plans to address and resolve complaints received through CMS' complaint tracking system and to provide a direct link on their main web page to the *Medicare.gov* electronic complaint form. We are proposing to modify §§ 422.504(a)(15) and 423.505(b)(22) by moving §§ 422.504(a)(15)(ii) and 423.505(b)(22)(ii) to subpart V, Communication requirements. Sections 422.111(h)(2) and 423.128(d)(2) require MA and Part D plans to maintain a website. In section VI.H. of this proposed rule, we are proposing to add a new §§ 422.2265 and 423.2265, which provides requirements for MA and Part D plan websites. Specifically, in §§ 422.2265(b) and 423.2265(b), we are proposing to identify the required content for websites, including a link to the *Medicare.gov* electronic complaint form. We believe the requirement for a direct link is more appropriate in CMS' website requirements rather than in §§ 422.504(a)(15) and 423.505(b)(22).

We are not proposing any substantive changes to §§ 422.504(a)(15) and 423.505(b)(22) other than minor changes in the text to make it clear that plans must use the CMS complaint tracking system to address and resolve complaints received by CMS against the plan. In connection with removing

§§ 422.504(a)(15)(ii) and 423.505(b)(22)(ii), we propose to redesignate the substance §§ 422.504(a)(15)(i) and 423.505(b)(22)(i) as §§ 422.504(a)(15) and 423.505(b)(22).

H. Advance Notice and Announcement of Part D Risk Adjustment Factors (§ 423.329)

The MMA, enacted on December 8, 2003, added a new ''Part D'' to the Medicare statute (sections 1860D–1 through 42 of the Act) establishing the Medicare Prescription Drug Benefit Program. The final provisions implementing the MMA for the MA and Part D programs appeared in the January 2005 final rule (70 FR 4588 through 4741 and 70 FR 4194 through 4585, respectively). The MMA directed that important aspects of the Part D program be similar to, and coordinated with law for, the MA program.

As is done in Part C, CMS uses risk adjustment factors to adjust a Part D plan's standardized bid amount. Risk adjustment accounts for the variation in plan liability for prescription drug costs that result from the demographics and health status of a plan's enrollees. In so doing, payments to plans reflect the beneficiaries they serve. The Part D statute, and the regulations implementing the statute, specify that CMS must publish the Part D risk adjustment factors at the time of publication of the Part C risk adjustment factors (section 1860D–15(c)(1)(D) of the Act and § 423.329(b)(4)). Part C risk adjustment factors are published through the Advance Notice and Rate Announcement process. By statute, the Part C factors are to be announced no later than the first Monday in April before the calendar year they will be in use (section 1853(b)(1)(B) of the Act and § 422.312(a)(1)(ii)). In addition, the statute requires CMS to give MA organizations advanced notice of proposed changes in methodology no later than 60 days prior to publishing the Rate Announcement, with a 30-day comment period.

In the vein of the MMA, which directed that important aspects of the Part D program be similar to, and coordinated with law for, the MA program, CMS interpreted section 1860D–15(c)(1)(D) of the Act to mean that Part D risk adjustment factors should be published as part of the Advance Notice and Rate Announcement process used for Part C. Since the inception of the Part D program in 2006, CMS has consistently proposed and finalized the Part D risk adjustment factors via the Advance Notice and Rate Announcement, respectively. The existing regulation codifying section 1860D–15(c)(1)(D) of the Act mirrors the statutory language of publishing Part D risk adjustment at the time of Part C risk adjustment factor publication but does not specify the means by which CMS will do so. The proposed amendment revises the regulation text to clarify our interpretation of the statute under which we will continue to publish Part D risk adjustment factors through the Advance Notice and Rate Announcement process. Specifically, we propose to amend the requirements at § 423.329(b)(4) by revising the paragraph to stipulate our intention to publish Part D risk adjustment factors using the process through which CMS proposes, adopts, and announces the capitation rates and risk adjustment methodology for the MA program. This provision codifies the current interpretation of the statutory requirement and will not change how we propose and finalize the Part D risk adjustment model. Therefore, it is not expected to have economic impact beyond current operating expenses. We are not scoring this provision in the Regulatory Impact Analysis section since it codifies statutory provisions that are followed in practice by the agency.

I. Advance Notice and Announcement of Part C Annual Capitation Rate, Benchmarks, and Methodology Changes (§ 422.312)

When enacted by the BBA of 1997, section 1853(b) of the Act mandated that the Secretary annually determine and announce capitation rates and the risk and other factors to be used in adjusting such rates for payment to Medicare Advantage (MA) organizations (then referred to as Medicare+Choice organizations). Section 1853(b) of the Act specifies the process through which CMS proposes, adopts, and announces changes in risk adjustment methodology and capitation rates for the MA program. Paragraph (b)(2) requires that CMS provide notice and an opportunity to submit comment on proposed changes to be made in the methodology from the methodology and assumptions used in the previous announcement. Paragraph (b)(1) provides for a final notice in which the rates and the risk and other factors used in adjusting payment will be published.

When first written, section 1853(b)(2) of the Act called for a 45 day advance notice period for the annual capitation rate and factors (for example, risk) used to adjust those rates and did not explicitly address a minimum comment period. However, beginning in 2017, amendments to section 1853(b) of the Act by the Securing Fairness in Regulatory Timing Act of 2015 (SFRTA) require a 60-day advance notice period and a 30-day comment period. The regulation implementing the advance notice and comment period, as currently written, mirrors the statute's original timeframe for issuance of the advance notice and requires only a 15-day comment period, which we adopted in the June 26, 1998, Medicare Program; Establishment of the Medicare+Choice Program Interim Final Rule with comment period (63 FR 34968, 35093) to adopt the initial implementing regulations for the MA program. While we adjusted our operational practice to comply with current statutory requirements, we did not update the CFR provision. The proposed revision will align the timeframes identified in § 422.312(b)(1) and (2) with the current statutory text. Specifically, we propose to revise the advance notice of changes in methodology requirements at § 422.312(b)(1) and (2) by revising paragraph (b)(1) to say 60 days and paragraph (b)(2) to say 30 days. We are not scoring this provision in the Regulatory Impact Analysis section since it codifies statutory provisions that are followed in practice by the agency.

J. General Requirements for Applicable Integrated Plans and Continuation of Benefits (§§ 422.629 and 422.632)

We propose to make technical changes to § 422.629(k)(4)(ii) to correct four technical errors from the April 2019 final rule. This paragraph references Medicare coverage criteria, however Medicaid coverage criteria are also applicable during the unified appeals process described in this section. Therefore, we are proposing to add the phrase ''and Medicaid'' following ''knowledge of Medicare'' in § 422.629(k)(4)(ii).

Also in paragraph (k)(4)(ii) of this section, there is an incorrect reference to the MA organization. We are proposing to replace ''MA organization'' with the correct term, ''applicable integrated plan''. We also propose adding the word ''integrated'' before ''organization determination decision'' to conform to the terminology used elsewhere in § 422.629(k). Lastly, we are also proposing to remove the comma between the words ''expertise'' and ''in'' in the regulation text to clarify that the required expertise is in the topics identified in the text.

In § 422.632(b)(1), we propose to change the citation from § 422.633(e) to (d). Section 422.632(b)(1) reflects the requirement that the enrollee file a

request for an integrated appeal in a timely manner, with a cross reference to the regulation that sets the timeframe for such appeals. Paragraph (d) of § 422.633 sets that timeframe while paragraph (e) addresses the requirements for expedited integrated reconsiderations. We are therefore proposing to amend § 422.632(b)(1) to use the correct cross-reference.

K. Representatives in Part D Appeals (§§ 423.560, 423.566, 423.578, 423.2014, and 423.2036)

The regulations for Medicare fee-for-service (Part A and Part B) claims and entitlement appeals at part 405, subpart I, reference two types of representatives—authorized and appointed. Section 405.902 defines an authorized representative as an individual authorized under state or other applicable law to act on behalf of a beneficiary or other party involved in an appeal, and separately defines an appointed representative as an individual appointed by a party to represent the party in a Medicare claim or claim appeal. The term ''representative'' is used throughout part 405, subpart I, to refer to either an authorized or appointed representative, except in some instances the regulations deal exclusively with appointed representatives. See, for example, §§ 405.910 and 405.1112(c).

Similarly, for appeals of Medicare Part C organization determinations, § 422.561 defines ''representative'' as an individual appointed by an enrollee or other party, or authorized under state or other applicable law, to act on behalf of an enrollee or other party involved in the grievance or appeal. The term ''representative'' is then used throughout part 422, subpart M, to refer to either an authorized or appointed representative.

For appeals of Medicare Part D coverage determinations, however, § 423.560 defines ''appointed representative'' as meaning either an individual appointed by an enrollee or authorized under state or other applicable law to act on behalf of the enrollee. The term ''appointed representative'' is then used throughout part 423, subparts M and U, to refer to either an appointed representative or an authorized representative. We believe that including authorized representatives in the definition of appointed representatives for Part D appeals is confusing since the terms represent two distinct types of representation and are treated separately in part 405, subpart I, and part 422, subpart M.

Accordingly, we are proposing to replace the definition of ''appointed representative'' in § 423.560 with a definition of ''representative.'' Although the term being defined would change, we are proposing no other changes to the definition. To be consistent with this proposed change, we are also proposing to replace references to appointed representatives in §§ 423.566(c)(2), 423.578(b)(4), 423.2014(a)(1)(ii), and 423.2036(c) and (d) with references to representatives. These proposed changes establish consistency in use of the term ''representative'' across Medicare programs. These provisions codify existing guidance and therefore are not expected to have economic impact beyond current operating expenses. We welcome comments on these proposed changes.

L. Copayments and Coinsurance in Amount in Controversy Calculations (§§ 422.600 and 423.2006)

Section 1869(b)(1)(E) of the Act, as amended by section 521 of BIPA, established the amount in controversy (AIC) threshold amounts for Administrative Law Judge (ALJ) hearings and judicial review at $100 and $1,000, respectively, for Medicare Part A and Part B appeals. Section 940 of the MMA amended section 1869(b)(1)(E) of the Act to require the AIC threshold amounts for ALJ hearings and judicial review to be adjusted annually. Section 940(b)(2) of the MMA provided conforming amendments to apply the AIC adjustment requirement to the amount in controversy thresholds applicable to appeals for Medicare Part C/Medicare Advantage (MA) plans and health maintenance organization and competitive health plans offered pursuant to section 1876 of the Act. Under § 405.840, health care prepayment plans offered pursuant to section 1833 of the Act are also subject to MA appeals rules, including the AIC adjustment requirement. Section 101 of the MMA provides for the application of the AIC adjustment requirement to Medicare Part D appeals.

The regulations at part 405, subpart I, specifically § 405.1006(d), provide the methodology for calculating the AIC in Medicare fee-for-service (Part A and Part B) claims and entitlement appeals. In general, and subject to the exceptions listed in §§ 405.1006(d)(2) through (6), § 405.1006(d)(1) provides that the AIC is computed as the amount that the provider or supplier bills (''the actual amount charged the individual'') for the items and services in the disputed claim, reduced by any Medicare payments already made or awarded for the items or services, and further reduced by ''any deductible and/or coinsurance amounts that may be collected for the items or services.''

For Medicare Part C appeals under part 422, subpart M, § 422.600(b) provides that the AIC is computed in accordance with the part 405 rules (concerning appeals of initial determinations under original (fee-for-service) Medicare). However, while original Medicare uses deductibles and coinsurance (where the beneficiary pays a percentage of the cost for an item or service) as forms of cost sharing, MA plans may also use copayments (where the enrollee pays a flat fee for an item or service) as a form of cost sharing. Because § 405.1006(d)(1) provides that the AIC excludes ''any deductibles and/or coinsurance amounts that may be collected for the items or services,'' questions have arisen regarding whether it is also appropriate to exclude any copayment amounts that may be collected for the items or services when applying the part 405 rules to appeals of Part C organization determinations made under part 422, subpart M. To resolve the ambiguity and help ensure that the AIC in Part C appeals is reflective of the actual amount at issue for the enrollee, we are proposing to revise § 422.600(b) to clarify that the AIC, which can include any combination of Part A and Part B services, is computed in accordance with part 405, and that any references to coinsurance in the part 405 regulations for computing the AIC should be read to include both coinsurance and copayment amounts.

We are also proposing a revision to the regulations for appeals of Part D plan sponsor coverage determination and at-risk determinations made under part 423, subpart M. The AIC for these appeals is addressed in § 423.2006, which does not reference cost-sharing amounts. Instead, current sub-regulatory guidance states that applicable deductible or coinsurance amounts are excluded from the AIC calculation in Part C and D appeals. *See* Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance (Parts C and D Appeals Guidance), section 70.2 (*https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf*). To clarify the AIC calculation for Part D appeals and help ensure that the AIC in Part D appeals is reflective of the actual amount at issue for the enrollee, we are proposing to revise § 423.2006 to reflect the AIC calculation provisions currently

set forth in the Parts C and D Appeals Guidance, further revised to exclude all cost-sharing amounts, including copayments. Specifically, we are proposing to redesignate paragraphs § 423.2006(c)(1) and (2) to (2) and (3), and amend (c)(1) to provide general AIC calculation provisions for Part D appeals, modeled after those in § 405.1006. This section will also provide that the AIC calculation is reduced by any cost-sharing amounts, including deductible, coinsurance, or copayment amounts, that may be collected from the enrollee for the Part D drug(s). This provision codifies existing guidance and is therefore not expected to have economic impact beyond current operating expenses.

M. Stipulated Decisions in Part C (§ 422.562)

The regulations for Medicare fee-for-service (FFS) (Part A and Part B) claims and entitlement appeals at part 405, subpart I provide for stipulated decisions at § 405.1038(c). This provision permits Office of Medicare Hearings and Appeals (OMHA) adjudicators to issue abbreviated, stipulated decisions if CMS or one of its contractors submits a written statement or makes an oral statement at a hearing indicating the item or service should be covered or payment may be made.[99] In this situation, an ALJ or attorney adjudicator may issue a stipulated decision finding in favor of the appellant or other liable parties on the basis of the written or oral statement, and without making findings of fact, conclusions of law, or further explaining the reasons for the decision.

The MA appeal regulations at § 422.562(d) provides-that the FFS appeals procedures in part 405, subpart I apply to appeals of Part C organization determinations to the extent they are appropriate and identifies specific part 405 regulations that are not appropriate to apply to MA appeals. Because MA organizations are not generally included within the definition of ''contractors'' in § 405.902, we are concerned it is not clear that § 405.1038(c) extends to stipulations made by MA organizations in Part C cases. The parallel Part D regulations for stipulated decisions at § 423.2038(c) specifically apply to stipulations made by Part D plan sponsors.

For consistency with the Part D regulations (which allow stipulations to be made by Part D plan sponsors under § 423.2038(c)), and to afford OMHA adjudicators the same flexibilities in Part C cases where the MA organization that issued the organization determination and plan reconsideration no longer disputes that an item or service should be covered or that payment should be made, we are proposing to revise § 422.562 by adding new paragraph (d)(3) to clarify that, for the sole purpose of applying the regulations at § 405.1038(c) to Part C appeals under part 422, subpart M, an MA organization is included in the § 405.902 definition of ''contractors'' as that definition relates to stipulated decisions issued by ALJs and attorney adjudicators. We believe this proposed clarification would permit OMHA adjudicators to more efficiently issue decisions where there is no longer any material issue in dispute, which would ultimately benefit MA enrollees because these decisions could potentially be issued, and effectuated by the MA organization, sooner. We solicit comment whether our proposed revision to add § 422.562(d)(3) this way raises unintended consequences for how the part 405 appeal rules apply to reviews at the ALJ of Part C appeals.

N. Beneficiaries With Sickle Cell Disease (SCD) (§ 423.100)

Section 1860D–4(c)(5)(C)(ii) of the Act contains exemptions from DMPs for certain beneficiaries. These exemptions are for an individual who receives hospice care, or is a resident of a long-term care facility for which FADs are dispensed for residents through a contract with a single pharmacy. We codified these exemptions contained in the definition of ''exempted individual'' in § 423.100. In addition, section 1860D–4(c)(5)(C)(ii)(III) of the Act provides the Secretary with the authority to elect to treat other beneficiaries as an exempted individual. Consistent with this authority and current clinical literature, CMS is proposing to add to the categories of exempted beneficiaries in § 423.100 those beneficiaries with SCD.

A recent analysis[100] by the Centers for Medicare & Medicaid Services Office of Minority Health identified 11,790 Medicare FFS beneficiaries in 2016 with SCD. The prevalence rate of SCD in the United States among the Medicare FFS population is 0.20 per 1,000 beneficiaries, of whom 72.6 percent were dually eligible for both Medicare and Medicaid. In April 2019, the CDC released guidance[101] that advised against the misapplication of the Guideline for Prescribing Opioids for Chronic Pain. Cited examples of misapplication included applying the Guideline to patients in active cancer treatment, patients experiencing acute sickle cell crises, or patients experiencing post-surgical pain. Based on these clinical guidelines and information, CMS recognizes the unique clinical nature of SCD, and as such believes that beneficiaries with this diagnosis should be exempted from DMPs given the: (1) Clinical nature of the disease; (2) unique presentation of SCD crises; (3) limited evidence to guide opioid administration in SCD; (4) limited knowledge of SCD among providers;[102] and (5) lack of other available therapies or modalities for treatment.

O. Drug Management Programs (DMPs): Additional Requirements (§ 423.153)

In an attempt to improve the clarity of the DMP regulations, CMS proposes the following wording and reference changes:

In the current DMP regulations, § 423.153(f)(3) states the types of coverage limitations on FADs that a Part D sponsor may implement and § 423.153(f)(3)(ii) specifically pertains to limitations to selected prescribers and pharmacies. Section 423.153(f)(9) through (13) pertain to the prescriber and pharmacy selection process. However, § 423.153(f)(3)(ii) references only paragraphs (f)(10) and (11). For completeness, we propose making a change to § 423.153(f)(3)(ii) so that it additionally references paragraphs (f)(9), (12), and (13). This provision is technical and is therefore not expected to have economic impact beyond current operating expenses.

In the current DMP regulations at § 423.153(f)(4), the regulation contains two inaccurate cross references. At § 423.153(f)(4)(ii)(A), a prescriber limitation is listed as existing in paragraph (f)(2)(ii)(B) of this section. This paragraph does not exist. Therefore, we are proposing to correct this reference to the intended paragraph: (f)(3)(ii)(A). In the same § 423.153(f)(4)(ii)(A), a reference to the section on eliciting information from

[99] For appeals in which the amount of payment is an issue before the ALJ or attorney adjudicator, § 405.1038(c) further provides that the written or oral statement must agree to the amount of payment the parties believe should be made.

[100] Wilson-Frederick SM, Hulihan M, Blaz J, et al. Prevalence of Sickle Cell Disease among Medicare Fee-for-Service Beneficiaries. CMS Office of Minority Health Data Highlight, No. 15. Baltimore, MD. 2019. Available from: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-15-Sickle-Cell-Disease.pdf.*

[101] Dowell D, Haegerich T, Chou R. N Engl J Med. 2019 Jun 13;380(24):2285–2287. doi: 10.1056/NEJMp1904190. Epub 2019 Apr 24. No abstract available. PMID:31018066. Available from: *https://www.nejm.org/doi/full/10.1056/NEJMp1904190.*

[102] *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Opioid-Prescription-in-Medicare-Beneficiaries-Report.pdf.*

prescriber lists paragraph (f)(4)(i)(B). CMS proposes correcting this reference to the intended paragraph, (f)(2)(i)(B). This provision is technical and is therefore not expected to have economic impact beyond current operating expenses.

Section 423.153(f)(8) addresses the timing and exceptions relevant to the beneficiary notice requirements. It provides that the second notice or alternate second notice must be provided on a date that is not less than 30 days, but does not clearly specify that this date is to be measured from the date of the initial notice. We propose to add this clarifying language to the paragraph. This provision is technical and is therefore not expected to have economic impact beyond current operating expenses.

In addition, § 423.153(f)(8) provides that the second notice or alternate second notice must be provided on a date that is not more than the earlier of two dates: (1) The date the sponsor makes the determination; or (2) 60 days after the date of the initial notice. No regulatory text is missing; however, we propose to structure the text to make it more readable and understandable.

The current DMP regulations on data disclosure at § 423.153(f)(15) are the basis for Part D sponsors' reports to OMS and MARx. Section 423.153(f)(15)(ii)(C) requires Part D sponsors to provide information to CMS about any potential at-risk beneficiary that meets paragraph (2) of the definition in § 423.100 that a sponsor identifies within 30 days from the date of the most recent CMS report identifying PARBs. A PARB meeting this definition refers to a beneficiary about whom a new plan sponsor receives notice upon the beneficiary's enrollment through the MARx system that the beneficiary was identified as potentially at-risk by the immediately prior plan sponsor under its DMP, but a coverage limitation on FADs had not yet been implemented by the prior plan before the beneficiary disenrolled.

As we explained in the applicable proposed and final rules,[103] in line with statutory requirements and previous opioid policy, we intended to also apply this requirement to at-risk beneficiaries (ARBs) who change plans. This intent is also reflected in our current policy and technical guidance,[104] as well as in current practice. CMS needs this information to properly oversee Part D drug management programs. Therefore, we propose to insert ''or at-risk beneficiary'' to this section. This means that Part D sponsors would be required to provide information to CMS about any ARB that is reported to the sponsor through MARx 30 days from the date of the most recent OMS report, as sponsors currently do in practice. This provision is technical and is therefore not expected to have economic impact beyond current operating expenses.

We would also like to take this opportunity to note mistakes in the Data Disclosure section of the Part D Drug Management Program Policy Guidance (November 20, 2018) on pages 30–31. In subsection I.2, we state that CMS has established the following procedures under which sponsors must share information about PARB 2s and ARB 2s. However, we clearly meant about PARBs and ARBs generally, as subsection I.2. details various data disclosures that Part D sponsors with DMPs must make about PARB 1s and ARB 1s also. In addition, in subsection I.2.b. on page 31, we state that a sponsor must provide coverage limitation information to CMS about PARB 2s and ARB 2s by entering information into MARx. Again, we meant PARBs and ARBs generally, as the subsection details information sponsors must enter into MARx about PARBs and ARBs and it is not limited to PARB 2s and ARB 2s. CMS needs this information in order to properly oversee Part D drug management programs, and this guidance is in line with existing § 423.153(f)(15)(ii)(D) which states that sponsors must provide information about initial notices (all PARBs) and second notices (all ARBs). We have not had an issue with Part D sponsors providing this information—only a question whether there were mistakes.

IX. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information,'' as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations, is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection requirement (ICR) should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule we are soliciting public comment on each of these issues for the following sections that contain proposed collection of information requirements. The provisions that are not discussed under this section of the preamble do not propose any new or revised collection of information requirements and/or burden and, therefore, are not subject to the requirements of the PRA. Please see section IX.C. of this proposed rule for the total burden implications.

A. Wage Data

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS's) May 2018 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 9 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

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[103] See pages 56359–60 of CMS–4182–P (November 28, 2017) and pages 16479–80 of the April 2018 final rule.

[104] See page 31 of the Part D Drug Management Program Policy Guidance (November 20, 2018). *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2019-Part-D-Drug-Management-Program-Policy-Guidance-Memo-November-20-2018-.pdf.*

TABLE 9: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Actuaries	15-2011	55.89	55.89	111.78
All Occupations [used for impact on enrollees filling out forms]	00-0000	24.98	n/a	n/a
Business Operations Specialist, all others	13-1199	37.00	37.00	74.00
Compliance Officer	13-1041	34.86	34.86	69.72
Computer Programmers	15-1131	43.07	43.07	86.14
Computer System Analysts	15-1121	45.01	45.01	90.02
Dietician	29-1031	29.43	29.43	58.86
Driver	53-3022	16.05	16.05	32.10
General Operations Manager	11-1021	59.56	59.56	119.12
Health Care Social Workers	21-1022	28.11	28.11	56.22
Home Care Coordinator (often a RN)	29-1141	36.30	36.30	72.60
Management Analyst	13-1111	45.38	45.38	90.76
Masters of Social Work	21-1022	28.11	28.11	56.22
Occupational Therapist	29-1122	41.04	41.04	82.08
Office Support and Administrative Support	43-9199	18.02	18.02	36.04
Medical and Health Services Managers (PACE Center Manager)	11-9111	54.68	54.68	109.36
Home Health Aides (Personal Care Attendant)	31-1011	12.18	12.18	24.36
Pharmacist	29-1051	59.45	59.45	118.90
Physical Therapist	29-1123	42.73	42.73	85.46
Primary Care Provider	29-1069	98.02	98.02	196.04
Recreational Therapist	29-1125	24.34	24.34	48.68
Registered Nurse	29-1141	36.30	36.30	72.60
Technicians, all other	19-4099	25.45	25.45	50.90

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As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Wages for Individuals: For beneficiaries, we believe that the burden will be addressed under All Occupations (at $24.98/hr) since the group of individual respondents varies widely from working and nonworking

individuals and by respondent age, location, years of employment, and educational attainment, etc. Unlike our private sector adjustment to the respondent hourly wage, we did not adjust this figure for fringe benefits and overhead since the individuals' activities will occur outside the scope of their employment.

B. Proposed Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within the preamble (see sections II through VIII) of this proposed rule.

1. ICRs Regarding Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§ 422.101)

The following proposed changes will be submitted to OMB for approval under control number 0938–1296 (CMS–10565). Subject to renewal, the control number is currently set to expire on June 30, 2022. It was last approved on June 30, 2019 and remains active.

This provision proposes to amend § 422.101(f) to implement the new requirements legislated by the BBA of 2018 to section 1859(f) of the Act for C–SNPs and to extend them to all SNP types. Specifically, we propose to add the following new regulations to account for new requirements governing SNP enrollee care management and SNP MOC submissions. The proposed regulations impacting MA SNP MOCs are as follows:

- We propose an amendment to § 422.101(f)(1)(i) following the end of the current text that would add the following language to the current regulation: ''and ensure that results from the initial and annual reassessment conducted for each individual enrolled in the plan are addressed in the individual's individualized care plan as required under paragraph (f)(1)(ii) of this section.'' In order to comply with this rule, MA SNPs would have to provide the necessary guidance to and develop related internal processes for employees of the SNP that are responsible for incorporating this requirement into their MOC.
- We propose a new regulation at § 422.101(f)(3)(ii)(A)–(C) to implement the requirement that: As part of the evaluation and approval of the SNP model of care, NCQA must evaluate whether goals were fulfilled from the previous model of care; plans must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment the previous MOC's goals; plans submitting an initial model of care must provide relevant information pertaining to the MOC's goals for review and approval; and if the SNP model of care did not fulfill the previous MOC's goals, the plan must indicate in the MOC submission how it will achieve or revise the goals for the plan's next MOC. Under this proposed regulation, each plan's MOC must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment the previous MOC's goals. Note, all SNPs are currently required to identify and clearly define measureable goals and health outcomes as part of their MOC under MOC 4, Element B: Measureable Goals and Health Outcomes for the MOC.
- Lastly, we propose a new regulation at § 422.101(f)(3)(iii) to implement the requirements that each SNP MOC submitted to CMS will be evaluated by NCQA based on a minimum benchmark (of 50 percent) for each of the existing four elements.

At the time SNP applications are due, MA organizations wishing to offer a new SNP will submit a MOC with their SNP application in the Application module in HPMS for NCQA review and approval. MA organizations wishing to renew their current SNP will submit a MOC in the MOC module in HPMS for NCQA review and approval. Based on their MOC scores, I–SNPs and D–SNPs receive an approval for a period of 1, 2, or 3 years. C–SNPs must renew their MOCs annually per section 1859(b)(6)(B)(iii) of the Act. For calendar year 2020, CMS received 273 SNP MOCs during the annual submission process and received 11 off-cycle submissions during the following time period. We believe these figures are representative of future SNP MOC submission totals going forward.

The burden related to the new requirements for SNP MOCs reflects the time and effort needed to collect the information as previously described, as well as all other MOC data, and report this information to CMS. To derive average costs, we selected the position of registered nurse because the SNP nurse usually develops and submits the MOC to CMS and typically interacts with the health plan quality registered nurse in matters related to the MOC after it is submitted to CMS.

The SNP will access HPMS and follow the appropriate instructions. The MA organization/SNP will click on the Application or MOC module in HPMS and download the SNP MOC Matrix document. The SNP will complete the document, and then upload its MOC matrix document with the MOC narrative. The SNP MOC Matrix upload document outlines the CMS SNP MOC standards and elements that must be addressed in the MOC narrative. The document also serves as a table of contents for the MOC narrative. Training to use the MOC module will be minimal at three hours annually, and training materials and non-mandatory webinar sessions are provided by CMS at no cost to the SNPs except for the time (and cost) to participate.

Using HPMS contract year 2020 submission data, for off-cycle submissions we estimate that 273 SNPs will submit MOCs annually. Note, this calculation is based on estimates that include annual MOC submissions for C–SNPs and semi-annual submissions for I–SNPs and D–SNPs. I–SNPs and D–SNPs submitting a MOC can receive MOC approval for one, two, or three year terms. For each SNP, we assume an additional 6 hours at $72.60/hr for a registered nurse. In aggregate, we estimate an ongoing annual burden of 1,638 hours (273 SNPs * 6 hr) at a cost of $118,919 (1,638 hr * $72.60/hr).

For plans seeking to revise their MOC based on qualifying events during the off-cycle season, we estimate that approximately 11 SNPs (D–SNPs/I–SNPs) will submit off-cycle MOC changes. For each SNP submitting off-cycle MOC changes, we assume an additional 4 hours at $72.60/hr for a registered nurse. In aggregate, we estimate an ongoing annual burden of 44 hours (11 SNPs * 4 hr) at a cost of $3,194 (44 hr * $72.60/hr).

Since the proposed § 422.101(f)(3)(iii) sets a minimum benchmark for each MOC element, we anticipate that there will be some impact to the number of MOC submissions that will not pass NCQA's initial MOC review. Looking at data for contract year 2020, our proposed element benchmark of 50 percent would have impacted 20 of the 273 MOCs submitted, or 7.3 percent. For contract year 2020, seven plans required submitting their MOCs for revision based on the current scoring system and an additional seven plans decided to withdraw their MOCs before the revision process for a total of 14 MOCs. The 14 SNPs must resubmit, taking 3 hours, or half the full 6 hour estimate. In aggregate, we estimate an added ongoing annual burden of 42 hours (14 SNPs * 3 hr) at a cost of $3,049 (42 hr * $72.60/hr).

For the aforementioned MOC requirements, we estimate an added annual burden of 1,724 hours (1,638 hr for MOC submissions + 44 hr for MOC revisions + 42 hr for MOC resubmissions) at a cost of $125,162 ($118,919 + $3,194 + $3,049, respectively).

Separate from the proposed changes to the MOC process, we propose a new regulation at § 422.101(f)(1)(iv) to implement a new requirement that plans provide face-to-face encounters with consenting individuals enrolled in the plan not less frequently than on an annual basis. The new regulation would require an annual face-to-face visit, that is, in-person or by remote technology such as telehealth, to occur starting within the first 12 months of enrollment within the plan. CMS would consider a visit to or by employed and/or contracted staff that perform clinical functions, such as direct enrollee care, as a qualifying encounter. Such activities may include, but are not limited to, annual wellness visits and/or physicals, HRA completion, meeting with the interdisciplinary team (IDT), care plan review, health-related education, and care coordination activities. It is also the expectation that any concerns related to physical, mental/behavioral health, and overall health status, including functional status, are addressed and any appropriate referrals, follow-up, and care coordination activities are provided or scheduled as necessary.

We believe that most, if not all, SNP enrollees will have a qualifying face-to-face encounter as proposed under § 422.101(f)(1)(iv) through an initial or annual HRA, a qualifying encounter with an IDT member, or an annual wellness visit. We estimate that approximately 734 SNPs that have at least 11 members will need to track face-to-face encounters for their enrollees annually. For each SNP tracking face-to-face encounters, we assume 4 hours of work by SNP personnel, typically a registered nurse. In aggregate, we estimate 2,936 hours (734 SNPs * 4 hr) at a cost of $213,154 (2,936 hr * $72.60/hr).

In addition, we propose to require in new § 422.101(f)(1)(iii) that MA organizations offering a SNP must provide each enrollee with an IDT in the management of care that includes a team of providers with demonstrated expertise, including training in an applicable specialty, in treating individuals similar to the targeted population of the plan. We propose that plans develop and implement this requirement into their MOC components to assure an effective management structure. We believe this requirement is consistent with currently approved information tracking practices for all existing SNPs, and thus, does not impose any new or revised ICRs and/or burden beyond what is currently approved by OMB under the aforementioned control number.

For the remaining proposed regulations under § 422.101(f)(2) and (3), SNP MOC submission requirements and burden are currently approved by OMB under said control number. The proposed changes would codify current guidance governing SNP MOC submission practices, which is captured under the active information collection request.

2. ICRs Regarding Contracting Standards for Dual Eligible Special Needs Plan (D–SNP) Look-Alikes (§ 422.514)

The following proposed changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267). Subject to renewal, the control number is currently set to expire on December 31, 2021. It was last approved on December 3, 2018 and remains active. The proposed requirements are associated with burden on MA plans identified as D–SNP look-alikes under § 422.514(d) (see section IX.B.2.a. of this proposed rule) and burden on the enrollees in these MA plans (see section IX.B.2.b. of this proposed rule).

As described in section II.E. of this proposed rule, we propose new contract requirements that we believe are necessary to fully implement D–SNP requirements, especially those related to Medicare-Medicaid integration codified at §§ 422.2, 422.107, and 422.629 through 422.634 pursuant to the BBA of 2018. We are proposing a prohibition on CMS entering into or renewing a contract for any non-SNP MA plan that an MA organization offers, or proposes to offer that:

- Projects in its bid submitted under § 422.254 that 80 percent or more of the plan's total enrollment are enrollees entitled to medical assistance under a state plan under Title XIX of the Act, or
- Has actual enrollment, as determined by CMS in January of the current year, consisting of 80 percent or more of enrollees who are entitled to medical assistance under a state plan under Title XIX of the Act, unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination.

Our proposed dually eligible enrollment threshold at § 422.514(d) would apply to any plan that is not a SNP as defined in § 422.2. We propose applying this requirement only to non-SNP plans to allow for the disproportionate dually eligible enrollment that characterizes D–SNPs, I–SNPs, and some C–SNPs by virtue of the populations that the statute expressly permits each type of SNP to exclusively enroll. The proposed requirement would also be limited to states where there is a D–SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals, such as MMPs. We propose this limitation because it is only in such states that the implementation of D–SNP requirements necessitates our proposed new contracting requirements. That is, in a state with no D–SNP or comparable managed care plan, the D–SNP requirements have not had any relevance historically, and therefore the operation of a D–SNP look-alike would not have any material impact on the full implementation of federal D–SNP requirements.

The proposed contract requirement based on the projected enrollment in the plan bid at § 422.514(d)(1) would prevent MA organizations from designing new D–SNP look-alikes. Under our proposal at § 422.514(d)(2), we would make the determination whether an MA organization has a non-SNP MA plan with actual enrollment exceeding the established threshold using the enrollment in January of the current year. Using data from the contract year 2020 bid submission process, we estimate that there are 67 MA plans that have enrollment of dually eligible individuals that is 80 percent or more of total enrollment. Of these 67 MA plans, 62 plans are in states where there are D–SNPs or comparable managed care plans and would be subject to § 422.514(d). These 62 plans project a total enrollment of 180,758 for contract year 2020.

MA organizations would likely terminate at the end of the plan year those plans that exceed our proposed criteria in § 422.514(d)(1) and (2). The MA organization would have the opportunity to make an informed business decision to transition enrollees into another MA plan by: (1) Identifying, or applying and contracting for, a qualified existing MA plan, including a D–SNP, in the same service area; or (2) creating a new D–SNP through the annual bid submission process. Alternatively, the terminating plan may choose to not transition enrollees.

The changes required of MA organizations based on this proposed rule would trigger collection of information by D–SNP look-alikes (see section IX.B.2.a. of this proposed rule) and their enrollees (see section IX.B.2.b. of this proposed rule). While we cannot predict the action of each affected MA organization, we base our proposed burden estimates on the current landscape of D–SNP look-alikes, the availability of D–SNPs or MA plans under the same parent organization in

the same service area, and the size and resources of the MA organization.

a. Burden on MA Plans

At § 422.514(e), we propose a process for transitioning individuals who are enrolled in a D–SNP look-alike to another MA–PD plan offered by the MA organization, or by another MA organization with the same parent organization as the MA organization, to minimize disruption as a result of the prohibition on contract renewal for existing D–SNP look-alikes. Under our proposal, an MA organization with a non-SNP MA plan determined to meet the enrollment threshold in proposed paragraph (d) could transition enrollees into another MA plan offered by the same MA organization (or by another MA organization with the same parent organization as the MA organization), as long as that MA plan meets certain proposed criteria. This process would allow an MA enrollee to be transitioned from one MA plan offered by an MA organization to another MA plan without having to complete an election form. Under this process, as described in § 422.514(e)(2), the MA organization would be required to describe changes to MA–PD benefits and provide information about the MA–PD plan into which the individual is enrolled in the Annual Notice of Change that the MA organization must send, consistent with § 422.111(a), (d), and (e) and proposed § 422.2267(e)(3).

Under § 422.514(e)(1), we propose to allow a terminating D–SNP look-alike to transition enrollment to another MA plan (or plans) only if the resulting total enrollment in each of the non-SNP MA plans receiving enrollment consists of less than 80 percent dually eligible individuals. This criterion would ensure that the enrollment transitions under this regulation do not result in another non-SNP MA plan being treated as a D–SNP look-alike under proposed § 422.514(d). Proposed § 422.514(e)(1)(ii) would require that any plan receiving transitioned enrollment be an MA–PD plan as defined in § 422.2. Proposed paragraph (e)(1)(iii) would require that any MA plan receiving transitioned enrollment from a D–SNP look-alike have a combined Part C and D premium of $0 after application of the premium subsidy for full subsidy eligible individuals described at § 423.780(a).

The proposed process at § 422.514(e) would allow, but not require, the MA organization to transition dually eligible enrollees from D–SNP look-alikes into D–SNPs and allow such enrollees to retain coverage under the MA organization and benefit from the care coordination and Medicaid benefit integration offered by a D–SNP. Proposed paragraph (e)(1) specifies that the MA organization could only transition individuals in a D–SNP look-alike into another MA plan (including a D–SNP) if they are eligible to enroll in the receiving plan. This proposed transition process is conceptually similar with ''crosswalk exception'' procedures proposed in section VI.C. of this proposed rule and in § 422.530(a) and (b); however, our proposal would allow the transition process to apply across contracts or legal entities and plan types (for example, non-SNP to SNP).

While the proposed prohibition on D–SNP look-alikes would only apply to plans starting in the 2022 plan year, we intend for the transition process to take effect in time for D–SNP look-alikes operating in 2020 to utilize the transition process for enrollments to be effective January 1, 2021. Based on the current landscape for D–SNP look-alikes, we believe the vast majority of these plans would be able to move current enrollees into another MA plan using the proposed transition process. By 2022, we expect that all 62 D–SNP look-alikes would choose to transition current enrollees to another MA plan for the forthcoming contract year. We estimate the burden for transitioning current enrollees to another MA plan at an average of 2 hours at $74.00/hr for a business operations specialist to submit enrollment changes to CMS. D–SNP look-alikes that transition enrollees into another MA plan would take less time than D–SNP look-alikes that transition eligible beneficiaries into a D–SNP. The 2-hour time estimate accounts for any additional work to confirm an enrollee's Medicaid eligibility for D–SNP look-alikes transitioning eligible enrollees to a D–SNP. For the estimated 62 D–SNP look-alikes, the one-time burden for transitioning enrollees to another MA plan by the 2022 plan year would be 124 hours (62 D–SNP look-alikes * 2 hr/response) at a cost of $9,176 (124 hr * $74.00/hr).

The vast majority of MA organizations with existing D–SNP look-alikes also have an MA plan with a premium of $0 or a D–SNP in the same service area as the D–SNP look-alike. Therefore, we do not believe MA organizations would choose to create a new D–SNP as a result of this proposed rule. The prevalence of existing MA plans and D–SNPs also make it unlikely that an MA organization would need to expand a service area for an existing MA plan or D–SNP. Since we estimate fewer than 10 respondents would apply as a new D–SNP or expand an existing MA plan service area, the information collection requirements are exempt under 5 CFR 1320.3(c) from the requirements of the PRA.

Additionally, we do not expect any plans would be required to send affected enrollees a written notice consistent with the non-renewal notice requirements at § 422.506(a)(2) and described at proposed § 422.514(e)(4), as we anticipate all MA organizations with D–SNP look-alikes would be able to transition their enrollees into another MA plan (or plans). However, we propose the requirement to ensure protection of enrollees if the situation did occur.

In subsequent years, we estimate that at most five plans per year would be identified as D–SNP look-alikes under § 422.514(d) due to meeting the enrollment threshold for dually eligible individuals or operating in a state that will begin contracting with D–SNPs or other integrated plans. We believe that these plans would terminate and transition their membership into another MA plan or a D–SNP. Therefore the annual burden after the 2022 plan year is estimated at 10 hours (5 plans * 2 hr/plan) at a cost of $740 (10 hr * $74.00/hr) for a business operations specialist to transition enrollees into a new MA plan. The impacts are summarized in Table 10.

b. Burden on MA Plan Enrollees

Proposed § 422.514(e)(2) would allow any individual transitioned from a D–SNP look-alike to another MA plan to stay in the MA plan receiving the enrollment or make a different election. The enrollees may choose new forms of coverage for the following plan year, including a new MA plan or services through the original Medicare fee-for-service program option and a Prescription Drug Plan (PDP). Because the proposed enrollment transition process would be effective on January 1 and notices would be provided during the annual election period, affected individuals would have opportunities to make different plan selections through the annual coordinated election period (prior to January 1) or the open enrollment period (after January 1). Additionally, dually eligible individuals qualify for a special election period at § 423.38(c).

We estimate that one percent of the 180,758 transitioning D–SNP look-alike enrollees would select a new plan or the original Medicare fee-for-service program and PDP option accepting the transition into a different MA plan or D–SNP under the same MA organization as the D–SNP look-alike they are currently enrolled in. Based on our experience

with passive enrollment of dually eligible beneficiaries into a new plan under the same parent organization for MMPs in the Financial Alignment Initiative, we estimate that 1,808 enrollees (180,758 transitioning D–SNP look-alike enrollees * 0.01), would opt out of their new plan for contract year 2021. Consistent with our currently approved burden estimates under the aforementioned control number, the enrollment process would require 0.5 hours. For this proposed rule, the total added burden for enrollees would be 904 hours (1,808 enrollees * 0.5 hr/response) at a cost of $22,582 (904 hr * $24.98/hr).

As stated previously, we believe that in subsequent years, at most five plans would be identified as D–SNP look-alikes and therefore this proposed regulation would have a much smaller impact on MA enrollees. Since the current 62 D–SNP look-alike plans have 182,758 enrollees in 62 plans, we estimate 14,577 enrollees (180,758 * 5/62) in five plans. Therefore, the maximum number of enrollees affected per year is estimated as 146 enrollees (14,577 total enrollees estimated in five plans * 0.01 who would select another plan). This would amount to a maximum annual burden of 73 hours (146 enrollees * 0.5 hr) at a cost of $1,824 (73 hr * $24.98/hr).

c. Summary

The burden for the proposed provisions are summarized in Table 10.

TABLE 10: SUMMARY OF BURDEN ESTIMATES FOR PROPOSED CONTRACT REQUIREMENTS AT § 422.514

Regulatory Citation	Subject	Number of Respondents	Number of Responses	Time Per Response (hr)	Total Hours (hr)	Labor Cost ($/hr)	Total Cost in 1st Year ($)	Total Cost in Subsequent Years ($)
§ 422.514(e)	Transition enrollees, 1st year	62	62	2	124.0	74.00	9,176	0
§ 422.514(e)	Transition enrollees, after 1st year	5	5	2	10.0	74.00	0	740
§ 422.514(e)	Filling out enrollment form 1st year	1,808	1,808	0.5	904.0	24.98	22,582	0
§ 422.514(e)	Filling out enrollment form after 1st year	146	146	0.5	73.0	24.98	0	1,824
TOTAL		2,021	2,021	*Varies*	1,111	*Varies*	31,758	2,564

3. ICRs Regarding Mandatory Drug Management Programs (DMPs) (§ 423.153)

The following proposed changes will be submitted to OMB for approval under control number 0938–0964 (CMS–10141). Subject to renewal, the control number is currently set to expire on November 30, 2021.

As discussed in section III.A. of this proposed rule, we propose to codify the statutory requirement that Part D plan sponsors establish DMPs by 2022. We also propose that, beginning in 2021, DMPs evaluate enrollees with a history of opioid-related overdose as potential at-risk beneficiaries (PARBs) that CMS reports to sponsors through the Overutilization Monitoring System (OMS).

As brief background on DMPs for context for this section, in general, the DMP requirements are codified at § 423.153(f). These provisions require Part D sponsors to conduct case management of PARBs identified by OMS through contact with their prescribers to determine if a beneficiary is at-risk for abuse or misuse of opioids and benzodiazepines.[105] After case management is completed, if a plan sponsor intends to limit a beneficiary's access to coverage of opioids and benzodiazepines, the sponsor must provide an initial written notice to the beneficiary and their prescribers. After the beneficiary has a 30-day time period to respond, the plan sponsor sends a second notice to the beneficiary, if the sponsor determines the beneficiary is an at-risk beneficiary (ARB), that the sponsor is implementing a coverage limitation on opioids and/or benzodiazepines, or an alternative second notice if the plan sponsor determines that the beneficiary is not an

[105] CMS currently designates both opioids and benzodiazepines as ''Frequently Abused Drugs'' for purposes of DMPs. See ''Part D Drug Management Program Policy Guidance'', November 20, 2018, p. 6; *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2019-Part-D-Drug-Management-Program-Policy-Guidance-Memo-November-20-2018-.pdf.*

ARB. Thus, every beneficiary who receives an initial notice receives a second or alternate second notice.

In 2019, a CMS analysis found that a majority of Part D contracts (669 of 779), or 85.9 percent) voluntarily included a DMP. Our proposal to codify the requirement that sponsors adopt DMPs would only affect the remaining minority of sponsors currently not offering such programs. There are 111 contracts (plan sponsors) run by 79 parent organizations that would be involved. Furthermore, we estimate that only 158 additional PARBs will be identified by these 111 contracts due to meeting the minimum OMS criteria. We estimate burden at the parent organization level because we believe that is a closer reflection of the number of systems that will need to be updated versus the contract level.

The estimated reporting burden to these sponsors has four aspects. Under § 423.153(f), sponsors must: (1) Design a DMP; (2) conduct case management, which includes sending written information about PARBs to prescribers; (3) program and issue written notices to PARBs and ARBs; and (4) disclose data to CMS about the outcome of case management via OMS and about any coverage limitation information into MARx.

For one-time initial development, we estimate it will take each parent organization without a DMP 80 hours for a team of clinical and non-clinical staff to design its DMP. Thus, we estimate 6,320 hours (79 parent organizations * 80 hr) program-wide for all remaining parent organizations to develop DMPs consistent with the requirements of § 423.153(f). We solicit comment as to the accuracy of these estimates.

We estimate that development will likely require two pharmacists (working at $118.90/hr) and two general operation managers (working at $119.12/hr) per organization. Thus, the hourly wage for the organization's development team is $476.04 [2 pharmacists * $118.90/hr] + [2 managers * $119.12/hr]. The labor rates for the development team is summarized in Table 11.

TABLE 11—LABOR RATES FOR THE DEVELOPMENT TEAM

Occupation	Adjusted hourly wage ($/hr)	Number of staff	Total wages ($/hr)
General operations manager	119.12	2	238.24
Pharmacist	118.90	2	237.80
Total	238.02	4	476.04

Therefore, each of the 79 parent organizations affected by this proposal will spend 80 hours at a cost of $38,083 (80 hr * $476.04/hr) for the team of four professionals to develop the DMP. The aggregate burden will therefore be 6,320 hours (79 parent organizations * 80 hr) at a cost of $3,008,573 (6,320 hr * $476.04/hr).

Once a DMP is developed and in place, the primary operations for impacted sponsors will involve case management by the sponsor to assess those enrollees reported as PARBs by CMS's OMS. The 111 contracts run by 79 parent organizations that did not voluntarily establish a DMP are generally smaller plans that in some cases offered alternative means of managing comprehensive beneficiary care, such as through PACE. They enroll only 410,000 Part D beneficiaries (less than 1 percent of total Part D enrollment in 2019). Accordingly, based on analysis of the first 3 quarters (January, April, and July 2019) of the OMS report data, we found that only 127 beneficiaries (about 0.7 percent) who met the minimum OMS criteria were not reported thus far in 2019 by CMS to the sponsors, because the sponsors did not have a DMP. Using this estimate, we can project that annually that about 158 beneficiaries would not be reported to their plan sponsors due to not having a DMP until DMPs become mandatory no later than January 1, 2022.

Once required DMP policies are developed and operational, sponsors would have to case-manage their PARBs (as outlined in § 423.153(f)(2)). The case management requirement includes a requirement that sponsors send written information to prescribers about PARBs. We estimated it would take an average of 5 hours for a sponsor to case-manage a PARB. We assume certain components of case management can be completed by staff of differing specialization and credentialing. We assume that 2 of the 5 hours on average would be conducted by a pharmacist (such as initial review of medication profiles, utilization, etc.) at $118.90/hr, 2 hours would be conducted by a health technician (''Technician, All other'') at $50.90/hr, and 1 hour would be conducted by a physician at $202.86/hr to work directly with providers on discussing available options and determining the best course of action. In aggregate, we estimate an annual burden for an estimated 158 enrollees annually newly subject to case management under this proposal to cost $85,708.68 per year (158 enrollees * ([2 hr * $118.90/hr for Pharmacists] + [2 hr * $50.90/hr for Technicians, All other] + [1 hr * $202.86/hr for Physician]).

The 79 Part D parent organizations affected by this proposal also would have to upload beneficiary notices into their internal claims systems before they could issue them. We estimate that it will take each, on average, 5 hours at $86.14/hr for a computer programmer to upload all of the notices into their claims systems (note, this is an estimate to upload all of the documents in total, not per document). In aggregate, we estimate a one-time burden of 395 hours (5 hr * 79 sponsors) at a cost of $34,025 (395 hr * $86.14/hr).

Since currently 5 percent of PARBs receive an initial and second notice (or alternate second notice), we estimate that 8 beneficiaries (158 beneficiaries * 0.05) would receive an initial notice and 8 would receive a second notice (or alternate second notice). Since fewer than 10 beneficiaries are affected by this, the burden of sending these notices is exempt from PRA.

As to disclosure of DMP case management outcomes data to CMS pursuant to § 423.153(f)(15), as stated earlier, the plan sponsors newly impacted by a mandatory DMP policy would be required to report to CMS the outcome of case management via OMS and any associated coverage limitation information into MARx. We estimate that it would take sponsors on average 1 minute (0.0167 hr) to report this information to OMS and MARx. In aggregate, we estimate an annual burden of 2.6386 hours (158 newly identified PARBs annually * 0.0167 hr) at a cost of $134 (2.6386 hr * $50.90/hr).

4. ICRs Regarding Beneficiaries With History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)

The following proposed changes will be submitted to OMB for approval under control number 0938–0964 (CMS–10141). Subject to renewal, the control number is currently set to expire on November 30, 2021.

Our proposal under § 423.100 to identify and report beneficiaries with a history of opioid-related overdose through OMS to Part D plan sponsors would mean that additional beneficiaries would be reported by OMS as PARBs. Based on July 2017 through June 2018 opioid-related overdose data, CMS's internal analysis estimates that about 18,268 enrollees meet the proposed criteria of an opioid-related overdose and would be PARBs. We project using this one-year estimate that in 2021 about 18,268 additional PARBs with an opioid-related overdose would be identified and reported by OMS. The estimated reporting burden associated with these new PARBs has three of the four aspects of the burden we estimated for mandatory DMPs, as previously described. Under § 423.153(f), sponsors must: (1) Conduct case management, which includes sending written information about PARBs to prescribers; (2) issue written notices to PARBs and ARBs; and (3) disclose data to CMS about the outcome of case management via OMS and about any coverage limitation information into MARx.

The assumptions surrounding case management by plan sponsors in the previous section were applied to the estimated population of 18,268 PARBs projected to be identified annually under this proposal. In aggregate, we estimate an annual burden for a projected 18,268 enrollees annually newly subject to case management, including sending the required written information to the prescribers of PARBs, under this proposal to cost $9,909,659.28 per year (18,268 enrollees * ([2 hr * $118.90/hr for Pharmacists] + [2 hr * $50.90/hr for Technicians, All other] + [1 hr * $202.86/hr for Physician]).

In order to estimate the impact of providing beneficiary notices, we compare two populations: (1) Part D beneficiaries projected to be potentially at-risk, by meeting the OMS criteria (which CMS estimates as 22,516 PARBs, based on internal data); and (2) beneficiaries with a history of opioid-related overdose (which CMS estimates as 18,268 PARBs, based on internal data).

We believe the population of beneficiaries with a history of opioid-related overdose would have a much higher rate of coverage limitations imposed by sponsors, due to the history of overdose being the risk factor most predictive for another overdose or suicide-related event.[106] We estimate that about 47.5 percent or 8,677 beneficiaries (18,268 beneficiaries * 0.475) of this population will receive an initial notice from the plan sponsor, informing the beneficiary of the sponsor's intention to limit their access to coverage of opioids and/or benzodiazepines. Thus, the beneficiary will also receive a second or alternate second notice informing them whether the limitation was in fact implemented.

This is in contrast to the PARBs meeting minimum and supplemental OMS criteria, where Part D program experience demonstrates a significantly lower incidence of coverage limitations (that is, only about 1,126 or 5 percent of the 22,516 beneficiaries receive notices).[107]

Following these assumptions, of the 40,784 (22,516 PARBs + 18,268 PARBs) Part D beneficiaries projected to be potentially at-risk, either by meeting the OMS criteria (22,516 PARBs) or the history of opioid-related overdose as defined (18,268 PARBs), those receiving a first notice from their plan sponsor informing them of the sponsor's intention to apply a coverage limitation are projected to total 9,803 enrollees (8,677 with history of opioid-related overdose + 1,126 meeting OMS minimum and supplemental criteria), or 24 percent of PARBs (40,784 * 0.24).

We estimate it would take 10 minutes (0.1667 hr) at $50.90/hr for a health technician to send two notices (each notice would require 5 minutes). In aggregate, we estimate an annual burden of 1,446 hours (8,677 enrollees * 0.1667 hr) at a cost of $73,601 (1,446 hr * $50.90/hr).

Evaluation of the use of POS claim edits under OMS since 2013 does not demonstrate a steady increase or decrease in edits. The OMS and POS edit reporting systems commenced in 2013 and 2014, and then between 2015 and 2018 the number of beneficiaries with opioid POS claim edits only ranged from 1,152 to 1,351 annually. As such, given that the vast majority of Part D enrollees are in a plan already offering a DMP, including the majority of Part D enrollees with a history of opioid-related overdose, we do not anticipate major shifts in the baseline average number of annual POS edits (and related initial notices). This stability in the annual number of ARBs and related notices to date appears largely unaffected by the baseline population of identified PARBs. However, we recognize that this proposed change is projected to approximately double the number of beneficiaries CMS identifies to sponsors as PARBs and accordingly solicit comment as to whether including beneficiaries with a history of opioid-related overdose and the projected doubling in identified PARBs is expected to require significant modifications by sponsors to respond to this increase in case management volume.

Model beneficiary notices[108] provided by CMS, as well as the required written information sent by sponsors to prescribers of PARBs as part of the case management process, would need to be revised to incorporate language specific to a PARB having a history of opioid-related overdose. For the model beneficiary notices, this includes updates to the sections defining DMPs and possible justifications for applying a coverage limitation. Proposed changes to the model beneficiary notices will be submitted to OMB for approval under control number 0938–0964 (CMS–10141). Additionally, sponsors may need to update their DMP prescriber written communications to include history of opioid-related overdose as a possible reason for a beneficiary meeting the OMS criteria. The changes needed to align the model beneficiary notices and the written communication are expected to be minimal.

We estimate it would take no more than 1 hour at $50.90/hr for a health technician to draft and implement such changes. In aggregate, we estimate a one-time burden of 288 hours (288 parent organizations * 1 hr/response) at a cost of $14,659 (288 hr * $50.90/hr). With respect to the burden of disclosure of DMP data to CMS associated with the increase in PARBs, we estimate that it will take sponsors on average 1 minute (0.0167 hr) at $50.90/hr for a health technician to document OMS and/or MARx the outcome of case management and any applicable coverage limitations.

[106] Bohnert KM, Ilgen MA, Louzon S, McCarthy JF, Katz IR. Substance use disorders and the risk of suicide mortality among men and women in the US Veterans Health Administration. Addiction. 2017 Jul; 11/2(7):1193–1201. doi: 10.1111/add.13774.

[107] CMS' internal analysis estimates that about 22,516 PARBs would meet the current OMS criteria based on 2018 data. An additional 18,268 PARBs are projected annually to meet the proposed criteria of opioid-related overdose.

[108] Notice documents available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Drug-Management-Program-Notices-.zip.*

In aggregate, we estimate an annual burden of 305 hours (18,268 PARBs * 0.0167 hr) at a cost of $15,525 (305 hr * $50.90/hr).

Table 12 summarizes the DMP provisions for which impact is discussed in sections IX.B.3. and IX.B.4. of this proposed rule.

TABLE 12: SUMMARY FOR MANDATORY DMPs AND IDENTIFICATION OF ADDITIONAL PARBs

Regulatory Citation	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost in 1st Year ($)	Total Cost in Subsequent Years ($)
§ 423.153	Creating DMP (those without DMPs)	79	79	80.00	6,320.0	476.04	3,008,573	0
§ 423.153	Upload Model Notices	79	79	5.00	395.0	86.14	34,025	0
§ 423.153	Conduct Case Management	79	158	1	158	542.46	85,709	85,709
§ 423.153	Disclosure to CMS	79	158	0.0167	2.6386	50.90	134	134
§ 423.100	Revise Model Notices	288	288	1.00	288.0	50.90	14,659	0
§ 423.100	Send Model Notices	288	8,677	0.1667	1446	50.90	73,601	73,601
§ 423.100	Conduct Case Management	288	18,268	1	18,268	542.46	9,909,659	9,909,659
§ 423.100	Disclosure to CMS (newly identified PARBs)	288	18,268	0.0167	305	50.90	15,525	15,525
TOTAL		288	1864	*Varies*	27,183	*Varies*	13,056,176	10,084,628

5. ICRs Regarding Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153) and Information on the Safe Disposal of Prescription Drugs

The following proposed changes to the MTM Standardized Format will be submitted to OMB for approval under control number 0938–1154 (CMS–10396). Subject to renewal, the control number is currently set to expire on August 31, 2020. The complete information collection request, which includes the proposed changes along with the unchanged provisions, will be posted for public review and comment (see section IX.D. of this proposed rule for further information).

Since the inception of the Medicare Part D benefit, the Act has required that all Part D plans offer a MTM program to eligible beneficiaries. The Act also established criteria for targeting beneficiaries for MTM program enrollment and a minimum set of services that must be included in MTM.

Under the current regulation at § 423.153(c), all MTM enrollees must be offered a Comprehensive Medication Review (CMR) at least annually and Targeted Medication Reviews (TMRs) no less than quarterly. A CMR is an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider that includes a review of the individual's medications and may result in the creation of a recommended medication action plan. An individualized, written summary in CMS's Standardized Format must be provided following each CMR. The SUPPORT Act expanded the population of beneficiaries that must be targeted for Part D MTM starting in 2021 and also added an additional requirement that information on the safe disposal of prescription drugs that are controlled substances be furnished to all MTM program enrollees; we are now proposing to modify our Part D regulations to conform with the changes to the MTM requirements enacted in the SUPPORT Act. These provisions of the

SUPPORT Act will affect the number of beneficiaries enrolled in MTM programs and potentially some of the content for the Standardized Format for the CMR and, therefore, the burden estimates for this document. We are estimating:

(A) The burden of the expanded population of beneficiaries that must be targeted for enrollment in MTM programs,

(B) the burden of mailing safe disposal information as part of the CMR summary, and

(C) the burden of mailing safe disposal information once a year as part of a TMR or another follow up service.

(A) The burden of the expanded population of beneficiaries that must be targeted for enrollment in MTM programs:

TABLE 13: ESTIMATED BURDEN OF TARGETING ARBs FOR MTM

Line ID	Item	Data	Source	Percentage of Part D Enrollees
(1)	Estimated number of Part D enrollees in 2021	48,338,879	Internal CMS data	N/A
(2)	Enrollees in the Enhanced MTM model tested by CMMI	1,550,300	Internal CMS data	3.2071%
(3)	Part D enrollees not in an Enhanced MTM program under the Enhanced MTM model	46,788,579	(1) * (2)	96.7929%
(4)	Number of Part D enrollees who are estimated to meet ARB criteria	10,000	Internal CMS data	N/A
(5)	Estimated number of ARBs in Enhanced MTM	321	Percentage in (2)*(4)	N/A
(6)	Number of ARBs who will be targeted for MTM	9,679	Percentage in (3)*(4)	N/A
(7)	Percent of targeted beneficiaries estimated to accept CMR offer under current MTMP	87%	Internal CMS data	N/A
(8)	Number of ARBs estimated to accept CMR offer under new provision	8,421	(6)*(7)	N/A
(9)	40 minutes is the industry standard for preparing a CMR	0.6667	Industry data	N/A
(10)	Number of hours needed to fulfill the preparation of CMRs including stuffing and mailing	5,614	(9)*(8)	N/A
(11)	Wage for a pharmacist to conduct a CMR	$118.90/hr	BLS Wage data	N/A
(12)	Cost to conduct CMRs for ARBs under the new provision	$667,505	(10)*(11)	N/A
(13)	Non-labor costs of cost of mailing: 6 pages * ($2.50/500 cost per page + $50/10000 cost of toner)+ 0.08 stuffing + 0.08 envelope + $0.70 for postage	$0.92	See narrative	N/A
(14)	Non-labor cost of mailing CMRs to ARBs	$7,747	(12)*(13)	N/A
(15)	Total cost for preparing and mailing CMRs to ARBs	$675,252	(12)+(14)	N/A

We estimate that in 2021 there will be 48,338,879 beneficiaries enrolled in Part D plans with MTM programs (line 1). Out of these, 1,550,300 (or 3.2071% = 1,550,300/48,338,879) are estimated to be enrolled in an Enhanced MTM program under the Enhanced MTM Model, which is a model tested by the Center for Medicare and Medicaid Innovation (the Innovation Center) under section 1115A(b) of the Act and is not subject to the current or proposed MTM requirements, and therefore these beneficiaries are excluded from the total number of Part D enrollees (line 2). This leaves 46,788,579 Part D enrollees (96.7929% = 46,788,579/48,338,879) who may be eligible for MTM if they meet the targeting criteria (line 3).

According to internal data, we estimate that the SUPPORT Act requires targeting 10,000 ARBs for MTM in 2021 (line 4), of which 9,679 (10,000 * 96.7929 percent of enrollees who are not in an enhanced MTM program) will be

targeted for a CMR (line 6) since those ARBs in the Enhanced MTM model plans (line 5) may not be targeted. Based on our previous experience with the MTM program, we estimate that 87 percent of beneficiaries targeted for MTM under the current requirements will accept the offer of a CMR (line 7). We assume this percentage will also apply to beneficiaries who will be enrolled in MTM programs under the new criteria; therefore, 8,421 ARBs (line 8) (9,679 targeted ARBs not in an enhanced MTM program * 87 percent who are expected to accept a CMR) are expected to accept a CMR based on the proposed provision.

To estimate the burden on Part D plans of furnishing CMRs to the 8,421 ARBs who would be expected to accept the offer of a CMR under the proposed policy, we separately calculate the non-labor cost of mailing and the labor cost of preparing the CMR and packaging it.

To estimate the cost of mailing, we note that paper costs $2.50 per ream (500 sheets) of paper (at $0.005 per sheet) and toner costs $50.00 and lasts for 10,000 sheets. Since CMR summaries contain private health information, they must be mailed first class for which postage costs $0.70 per mailing. Based on industry standards, we assume envelopes cost $0.08, and folding and stuffing costs about $0.08 per document. We therefore estimate the non-labor cost to print and mail a CMR summary in CMS's Standardized Format will be $0.92 per mailing (line 13). This results in a cost of $7,747 (line 14) ($0.92 cost per mailing * 8,421 ARBs).

To estimate the labor cost of preparing the CMS, we note that the CMR is a clinical consultation service and therefore must be administered by a pharmacist, physician, nurse practitioner, or other clinician. Currently, 100% percent of MTMPs employ pharmacists to conduct CMRs, which is the basis of the hourly rate estimate. Industry standards indicate that an average CMR requires 40 minutes or 0.6667 hours (line 9) at $118.90/hr (line 11) for a pharmacist to complete and would result in a CMR summary that averages 6 pages in length based on proposed revisions which would streamline the Standardized Format. This is a decrease in length from the currently approved Standardized Format which averages 10 pages. This results in an annual labor burden of 5,614 hours (line 10) (8,421 ARBs * 0.6667 hours) at a cost of $667,505 (line 12) (5,614 hours * $118.90/hr).

Therefore, the estimated total annual cost of providing CMRs to 8,421 ARBs would be $675,252 (line 15) ($667,505 labor costs + $7,747 non-labor mailing costs). These calculations are summarized in Table 13.

(B) The burden of mailing safe disposal information as part of the CMR summary:

TABLE 14: ESTIMATED BURDEN FOR MAILING SAFE DISPOSAL INFORMATION AS PART OF THE CMR

Line ID	Item	Data	Source
(16)	Part D enrollees not in an Enhanced MTM program under the Enhanced MTM model	46,788,579	(3)
(17)	ARBs not in an Enhanced MTM program under the Enhanced MTM model	9,679	(6)
(18)	Part D enrollees that are neither in Enhanced MTM nor meet ARB criteria	46,778,900	(16)-(17)
(19)	Percentage of Part D enrollees who meet the current criteria for MTM	5.34%	Internal CMS data
(20)	Estimated number of Part D enrollees not in an Enhanced MTM program under the Enhanced MTM model and not meeting ARB criteria who are targeted for MTM under the current criteria	2,497,993	(18)*(19)
(21)	Percent of enrollees targeted for a CMR under the current criteria who accept the offer	87%	Internal CMS data
(22)	Estimated Part D enrollees under the current criteria who will receive a CMR	2,173,254	(20)*(21)
(23)	Estimated Part D enrollees under the proposed provisions meeting ARB criteria who will receive a CMR	8,421	(8)
(24)	Total Part D enrollees (under the current and proposed rule) who will receive a CMR	2,181,675	(22)+(23)
(25)	Non-labor costs of one extra page (2.50/500) and toner for one page ($50/10,000)	$0.01	See narrative
(26)	Estimated cost of mailing safe disposal items to those receiving a CMR (under assumption that the plan will bundle the safe disposal and CMR)	$21,817	(24)*(25)

Under our proposed regulatory change to § 423.153(d)(1), Part D plans would be required to provide all MTM enrollees with information about safe disposal of prescription medications that are controlled substances. The proposed provision would allow plans to mail the newly required safe disposal information either as part of the CMR summary or as part of a TMR or other follow-up service. We estimate the safe disposal information will take one page, has no personal information, and can for example be mailed out as a standalone flier if not included in the annual CMR.

However, for those enrollees receiving a CMR, we believe it most economical to include the 1 page with the already existing CMR summary. We solicit industry input on the accuracy of this assumption. Therefore, the cost of mailing one extra page per enrollee is $0.01 (line 25) (1 page * $2.50/ream of 500 sheets + 1 page * $50 toner/10,000 sheets). We note that the envelope to mail the CMR is already being paid for under current regulations (although folding and stuffing of 7 pages versus 6 pages might require some extra effort, we do not believe this will raise the $0.08 current cost but solicit stakeholder comment on this assumption); the $0.70 first class postage for 2 ounces is sufficient for 7 pages (there would be no increase in postage).

To estimate total mailing cost, we must add the estimates of i) total number of Part D enrollees not in an Enhanced MTM program under the Enhanced MTM model and who are not ARBs who will receive a CMR under the current criteria and ii) total number of ARBs who will receive a CMR under the proposed criteria.

(i) As shown in Table 13, lines (3) and (6), we estimate that in 2021, there will be 46,788,579 Part D enrollees not in an Enhanced MTM program under the Enhanced MTM program (line 16) and as previously determined, 9,679 of those will meet the new MTM targeting criteria as ARBs (line 17). This leaves 46,778,900 Part D enrollees (46,788,579 not in an Enhanced MTM program minus 9,679 enrollees meeting the ARB criteria) that must be targeted for MTM if they meet the current criteria (line 18). Our internal data shows that 5.34 percent (line 19) of the Part D enrollees will be targeted for MTM programs under the current criteria. Hence, this leaves 2,497,993 Part D enrollees (5.34 percent * 46,778,900) who will be targeted for MTM under the current criteria (line 20). Of these 2,497,993 targeted enrollees, as stated previously, based on internal CMS data, we estimate 87 percent will accept the annual CMR offer (line 21). Therefore 2,173,254 beneficiaries (2,497,993 * 0.87) will receive a CMR under the current criteria (line 22).

(ii) As shown in Table 13, line (8), 8,421 ARBs are estimated to receive a CMR under the proposed criteria.

Hence, in 2021 a total of 2,181,675 enrollees will receive a CMR under the current and proposed criteria (8,421 ARBs under the proposed criteria + 2,497,993 under the current criteria) (line 24), at a total non-labor mailing cost of $21,817 (2,181,675 enrollees * $0.01 mailing cost per enrollee) to add an additional page containing safe disposal information to all CMRs (line 25).

These calculations are summarized in Table 15.

(C) The burden of mailing safe disposal information once a year as part of a TMR or other follow-up service:

TABLE 15: BURDEN OF MAILING SAFE DISPOSAL INFORMATION TO ENROLLEES NOT RECEIVING A CMR

Line ID	Item	Data	Source
(27)	Number of Part D enrollees who meet the current criteria for MTM	2,497,993	(20)
(28)	Number of Part D enrollees who meet the criteria for ARB under the proposed rule	9,679	(6)
(29)	Number of Part D enrollees meeting current or proposed criteria for MTM	2,507,672	(27)+(28)
(30)	Percentage of enrollees estimated to refuse the offer of a CMR	13%	100% - (21)
(31)	Number of enrollees to whom safe disposal information must be mailed even though they don't receive a CMR	325,997	(29)*(30)
(32)	Non-labor cost of mailing a one page flier (at 2.50/500 cost per page + $50/10000 cost of toner for one page + $0.19/200 cost of mailing a flier)	$0.01095	See narrative
(33)	Cost of mailing safe disposal information to those who do not receive a CMR	$3,570	(31)*(32)
(34)	Cost of mailing safe disposal information to those who do receive a CMR	$21,817	(26)
(35)	Total cost of mailing safe disposal information	$25,387	(33)*(34)

All targeted beneficiaries who have not opted out of the MTM program must receive TMRs at least quarterly, and we are allowing Part D sponsors the flexibility of choosing whether to include safe disposal information in the CMR, through a TMR, or another follow-up service at least once annually. Since we assume that 87 percent of targeted enrollees accept an offer of a CMR (Table 13, line (7)), it follows that 13 percent (100 percent − 87 percent) (line 30) of Part enrollees who are targeted for enrollment in an MTM program refuse the CMR offer but do not opt out of the MTM program completely. As discussed previously, 9,679 ARBs (Table 13, line (6)) under the proposed criteria and 2,497,993 enrollees (Table 14, line 20) under the current criteria, or a total of 2,507,672 enrollees (2,497,003 + 9,679) (line (29)) will be targeted to receive a CMR. Therefore 325,997 enrollees (2,507,672 total enrollees * 13 percent who refuse a CMR) would need to be mailed the safe disposal information as part of a TMR or other follow-up service (line 31). The cost to mail 1 page of safe disposal information is $0.01095 per enrollee if the letter does not contain private health information and thus bulk mailing is used (line 32) (1 page * $2.50 per ream of paper/500 sheets + 1 page * $50 per toner/10,000 pages + $0.19/200 items). Therefore, the estimated cost of mailing safe disposal information to those MTM enrollees who do not receive a CMR is $3,570 (line 33) (325,997 enrollees * $0.01095 mailing cost per page).

The total cost of mailing safe disposal information to all Part D beneficiaries enrolled in MTM programs is then estimated to be $25,387 (line 35) ($3,570 for those enrollees who refuse a CMR + $21,817 for those enrollees who accept a CMR). These calculations are summarized in Table 15.

The total additional annual cost for 288 parent organizations to provide CMRs to ARBs and to send safe disposal information of prescription medications that are controlled substances to all MTM program enrollees is $700,369.

Table 16 provides a compact summary of the bottom lines of impact by activity.

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TABLE 16: SUMMARY FOR ELIGIBILITY FOR MTMPs (§ 423.153) AND INFORMATION ON THE SAFE DISPOSAL OF PRESCRIPTION DRUGS

Regulatory Citation	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
§ 423.153	Mailing ARBs CMR	288	8,421	N/A	N/A	0.92	7,747
§ 423.153	Targeting ARBs for CMR	288	8,421	0.6667	5,614	118.90	667,505
§ 423.153	Safe Disposal Page in CMR	288	2,181,675	N/A	N/A	0.010	21,817
§ 423.153	Safe Disposal Page as part of TMR or other follow-up service	288	325,997	N/A	N/A	0.01095	3,570
TOTAL		288	2,507,672	5,614	*Varies*	*Varies*	700,639

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6. ICRs Regarding Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)

In this rule, we are proposing under § 423.128 to require Part D sponsors to disclose, beginning 2021, information about the risks of prolonged opioid use to enrollees. In addition to this information, Part D sponsors of MA–PDs must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans and under Medicare Part C. Part D sponsors of PDPs must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans and under Medicare Parts A and B.

Before Part D sponsors can send this information, they would have to create and upload materials into their internal systems. Based on 2019 CMS data, there are 608 Part D legal entities (sponsors) with which CMS contracts, associated with 288 parent organizations that these contracts identified in their initial applications, which is confirmed annually. Based on our knowledge of the way parent organizations and their Part D legal entities are structured, we believe it is appropriate to estimate burden at the parent organization level, as it is a closer reflection of the number of systems that will need to be updated versus at the contract level.

We estimate that 288 Part D sponsors would be subject to this proposal, based on 2019 data. We estimate that it will take on average 2 hours at $86.14/hr for a computer programmer to upload the

information into the systems. This would result in a one-time burden of 576 hours (2 hr * 288 parent organizations) at a cost of $49,617 (576 hours * $86.14/hr). Once the information is uploaded into the parent organization's database, we anticipate no further cost associated with this task, as the process will be automated after the initial upload with the same information on subsequent materials that are sent. The automation would include the sending of information to those enrollees who wish to receive an electronic copy. The automation would also cover updates in future years as the plan enrollment changes.

We also estimate a one-time burden of 2 hours at $118.90/hr for a pharmacist to develop the materials(s) to be sent to the beneficiaries. In aggregate, we estimate a one-time burden of 576 hours (288 parent organizations * 2 hr) at a cost of $ 68,486 (576 hr * $118.90/hr). Although there might be the need for updates in future years (if opioid risk and/or coverage information changes), we believe the burden to making such updates to existing materials will be negligible as the changes will be minor and may only occur in some future years. Hence, the more accurate approach adopted here is to estimate this as a one-time update.

We propose that Part D sponsors may disclose the opioid and coverage information in electronic form. Some enrollees prefer electronic notification and some prefer paper mailing. We have no way of estimating the proportions for each preference, but our experience suggests that most enrollees expect a paper mailing. Therefore, we assume 75 percent (the average of 50 percent and 100 percent) would prefer a paper mailing, while the remaining 25 percent would prefer electronic notification.

There are several Part D enrollee groups presented in section III.D. of this proposed rule that we suggest could be sent the required information and thus, several approaches to estimate the burden. These enrollee group estimates range from sending the information to 46,759,911 enrollees to 2,698,064 enrollees, Therefore, for plans convenience and planning, Table 17 presents an alternative cost analysis of the wide range of alternatives discussed in section III.D. of this proposed rule.

We also include calculations under assumption that only 50 percent want paper and calculations under assumption that 75 percent want paper. As can be seen, the range of costs are $0.1 to $0.5 million (for sending notices by paper to all Part D enrollees. Thus, cost need not be a factor in plan choice.

Since the range of costs are $0.1 million to $0.5 million, for purposes of the Summary Table, we are listing the $0.1 million or $118,103 first year cost ($68,486 for creation of materials + $49,617 for system updates) but leaving out mailing costs until we receive feedback from our stakeholders. We however, solicit stakeholder feedback on which alternatives they believe are most likely and unlikely, as well as stakeholder feedback on our estimation of printing and delivery costs.

In making estimates on the burden of sending out notices, we assume that the IT systems of the plan would generate and mail the documents once a template is produced. Thus, the only costs per enrollee are paper, toner, and postage. We also assume one page per notice. We therefore estimate:

- *Cost of paper:* Typical wholesale costs of paper are approximately $2.50 for a ream of 500 sheets. Thus cost for one page is 2.50/500 = $0.005.
- *Cost of toner:* Toner costs can range from $50 to $200 and each toner can last 4,000 to 10,000 sheets. CMS assumes a cost of $50.00 for 10,000 pages. Thus cost per page is $50/10,000 = $0.005.
- *Cost of postage:* For 2019, the bulk postage rates are $0.19 per 200 pages. Thus the cost per page is 0.19/200 = 0.000950.

Thus, the aggregate cost per page is 0.01095 (0.005 + 0.005 + 0.000950). This per page amount is multiplied by the number of enrollees receiving the notification. Note that mailing costs are annual while the programming updates and the development of materials are first-year costs with minimal or no costs in future years. The product of the cost per page times the number of enrollees plus the first year costs are the costs listed for each possibility in Table 17.

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TABLE 17: IMPACTS OF SEVERAL ALTERNATIVES FOR PROVIDING INFORMATION TO OPIOID USERS

(A) Issue	(B) Number of Opioid Users in this Category	(C) Number of Part D Sponsors	(D) Percentage of Enrollees Wanting Paper Delivery	(E) Cost per Plan or Enrollee for Paper Copies	(F) Aggregate Cost (B)*(D)*(E)	(G) Total Cost for this Scenario	Total Cost Rounded (millions)
2 hours of programming	N/A	288	N/A	172.28	49,617	N/A	N/A
2 hours for a pharmacist to develop the materials	N/A	288	N/A	237.8	68,486	N/A	N/A
Total first year programming and development cost	N/A	N/A	N/A	N/A	118,103	N/A	N/A
75% want paper; 90-day usage with 7 day (or less) gap	2,698,064	N/A	75%	0.01095	22,158	140,261	0.1
50% want paper; 90-day usage with 7 day (or less) gap	2,698,064	N/A	50%	0.01095	14,772	132,875	0.1
75% want paper; 30-day usage with 7 day (or less) gap	3,816,731	N/A	75%	0.01095	31,345	149,448	0.1
50% want paper; 30-day usage with 7 day (or less) gap	3,816,731	N/A	50%	0.01095	20,897	139,000	0.1
75% want paper; 7-day usage	7,163,615	N/A	75%	0.01095	58,831	176,934	0.2
50% want paper; 7-day usage	7,163,615	N/A	50%	0.01095	39,221	157,324	0.2
75% want paper; All opioid users (1 year)	11,027,271	N/A	75%	0.01095	90,561	208,665	0.2
50% want paper; All opioid users (1 year)	11,027,271	N/A	50%	0.01095	60,374	178,477	0.2
75% want paper; any opioid use in last 2 years excluding cancer and hospice patients	16,134,063	N/A	75%	0.01095	132,501	250,604	0.3
50% want paper; any opioid use in last 2 years excluding cancer and hospice patients	16,134,063	N/A	50%	0.01095	88,334	206,437	0.2
75% want paper; All Part D enrollees	46,759,911	N/A	75%	0.01095	384,016	502,119	0.5
50% want paper; All Part D enrollees	46,759,911	N/A	50%	0.01095	256,011	374,114	0.4

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The burden associated with developing and uploading these materials into sponsors' internal systems will be submitted to OMB under PRA package number CMS–10141 (OMB 0938–0964). Subject to renewal, it is currently set to expire on November 30th, 2021. It was last approved on November 28, 2018, and remains active.

7. ICRs Regarding Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

The following proposed changes will be submitted to OMB for approval under control number 0938–TBD (CMS–10724) for Medicare Advantage Plans and 0938–1262 (CMS–10517) for Part D Plans.

Proposed §§ 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*) would require the MA organization or Part D plan sponsor, respectively, to have procedures to identify and report to CMS or designee: (1) Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy; which must be implemented in the same manner as the Secretary does under 1862(o)(1) of the Act; and (2) any information related to the inappropriate prescribing of opioids and concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan.

CMS initiated a reporting pilot program in December 2016 with six plan sponsors to test the effectiveness of mandatory reporting of fraud, waste and abuse. The pilot collected all external or internal Medicare complaints and referrals submitted to the plan's Special Investigations Unit (SIU). The data collected as part of the pilot program was time limited, but broader than the scope of reporting required by sections 2008 and 6063 of the SUPPORT Act. The scope of that pilot tested the reporting of all types of health care fraud, waste, and abuse that the plan sponsors could encounter in their operations and, therefore, could be utilized as a reasonable estimate of burden involved with the quarterly plan reporting to CMS that CMS will use to implement sections 2008 and 6063 of the SUPPORT Act. The pilot program analyzed information that was reported from five of six plan participants on time spent collecting three quarterly data submissions. Based on the results of the pilot study, if every plan reported, we estimate it would take 605 MA plans and 63 Part D plans 164,996 hours (668 plans * 247 hr/plan) at a cost of $14,975,037 (164,996 hr * $90.76/hr) to fulfill the proposed reporting and procedure preparation in the first year. The first-year costs consist of the time and effort needed to prepare the procedures and report the inappropriate prescribing information. Subsequent effort consists solely of the ongoing time and cost to report the inappropriate prescribing information to CMS. We cannot anticipate how many plans will need to report any payment suspension to pharmacies in the plans' network or information on inappropriate opioid prescribing to CMS.

In subsequent years, we estimate an annual burden of 104,208 hours (668 plans *156 hr/plan) at a cost of $9,457,918 (104,208 hr * $90.76/hr).

The following Tables 18 and 19 show—

- MA Organization and Part D Plan Sponsor Time Estimate (HOURS) (Table 18); and
- MA Organization and Part D Plan Sponsor Cost Estimate ($) (Table 19).

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TABLE 18: MA ORGANIZATION AND PART D PLAN SPONSOR TIME ESTIMATE (HOURS)

OMB Control Number (CMS ID No.)	Requirements	Number of Respondents	Total Burden Hours (Initial Year)[2]	Total Burden Hours (Subsequent Years)[2]
0938-TBD (CMS-10724)	MA Organizations: § 422.503(b)(4)(vi)(G)(*4*)	605	149,435	94,380
0938-1262 (CMS 10517)	Part D Plans: § 423.504(b)(4)(vi)(G)(*4*)	63[1]	15,561	9,828
TOTAL		668	164,996	104,208
FIRST YEAR BURDEN:			**164,996 (668 plans * 247 hr/plan)**	
SUBSEQUENT YEARS ANNUAL BURDEN:			**104,208 (668 plans* 156 hr/plan)**	

[1] Total number of PDPs in 2020 determined through a review of HPMS; the total number excludes PACE plans who are not required to report via HPMS.

[2] Burden Hours: Utilizing the pilot as a basis for the burden calculation, it should be noted that a higher level of effort (plan burden) was required for the first data submission as plan sponsors became familiar with the data fields and mapped their data. However, the following data submissions required a significantly reduced level of effort. The first year as previously shown reflects that higher level of effort, 247 hours per plan. For each future year, the estimate is shown at 156 hours per plan.

Note: (1) The estimates are based on the reporting structure, as outlined in our proposals; (2) the reporting will occur at the contract level; (3) the number of plans does not include PACE plans.

TABLE 19: MA ORGANIZATION AND PART D PLANS COST ESTIMATE ($)

OMB Control Number (CMS ID No.)	Requirements	Number of Respondents	Time Burden (Initial Year)[1]	Hourly Rate ($/hr)[2]	Total Annual Burden ($)
0938-TBD (CMS-10724)	MA Organizations: § 422.503(b)(4)(vi)(G)(*4*)	605	149,435	90.76	13,562,721
0938-1262 (CMS 10517)	Part D Plans: § 423.504(b)(4)(vi)(G)(*4*)	63	15,561	90.76	1,412,316
	FIRST YEAR BURDEN		164,996	90.76	**14,975,037**
	BURDEN IN EACH SUBSEQUENT YEAR	668 Total Plans	104,208	90.76	**9,457,918**

[1] Burden Hours (Initial Year): Utilizing the pilot as a basis for the burden calculation, it should be noted that a higher level of effort (plan burden) was required for the first data submission as plan sponsors became familiar with the data fields and mapped their data. However, the subsequent data submissions required a significantly reduced level of effort.

[2] Using wages of Management Analyst (Occupational title 13-1111).

Note: (1) The estimates are based on the reporting structure, as outlined in our proposals; (2) the reporting will occur at the contract level; (3) the number of plans does not include PACE plans.

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8. ICRs Regarding Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

As discussed in section IV.A. of this proposed rule, we propose to revise §§ 422.50(a)(2), 422.52(c), and 422.110(b) to allow ESRD beneficiaries, without exception, to enroll in an MA plan. In estimating the impact of this provision, we separately estimate impact on beneficiaries and plans. Enrollment processing and notification requirements are codified at § 422.60 and are not being revised as part of this rulemaking, and no new or additional ICRs are being imposed. The additional paperwork burden for this provision to account for ESRD beneficiaries to enroll in a MA plan, as outlined in the next section, will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267). Subject to renewal, the control number is currently set to expire on December 31, 2021.

a. Beneficiary Burden

The burden associated with this requirement would be related to the effort it takes for a beneficiary to complete an enrollment request. Because there will be an increase in the number of beneficiaries eligible to elect an MA plan starting in plan year 2021, the universal burden for beneficiaries would increase (that is, the number of beneficiaries who are expected to initiate an enrollment action would increase). However, the currently approved response time estimate (0.5 hr) would not change.

To elect an MA plan, an individual must complete and sign an election form, complete another CMS-approved election method offered by the MA plan, or call the 1–800–MEDICARE Call Center, and provide information required for enrollment. The burden associated with this requirement is the time it takes a new enrollee to complete an enrollment form or other CMS-approved election method offered by the MA plan. The enrollment form and other election methods vary for each organization, but similar identifying information is collected.

As detailed in section X.C.4. of this proposed rule, OACT expects an average increase of 59,000 ESRD beneficiaries to enroll in MA plans per year in 2021 through 2023. Therefore, we expect a burden of 29,500 hours (59,000 new ESRD enrollees * 0.5 hr) to complete an enrollment form at a cost of $736,910 (29,500 hr * $24.98/hr).

CMS is proposing changes to the current, standard (''long'') model form used for MA and PDP enrollment in order to reduce data collection and simplify the enrollment process. CMS is not revising the current, ''long'' model form under CMS–R–267. The ''shortened'' enrollment form, three pages in length, (compared to the current model form which is seven pages), would limit data collection to what is lawfully required to process the enrollment, and, other limited information that the sponsor is, required or chooses to, provide to the beneficiary. A new ''stand-alone'' PRA notice (CMS–10718, OMB 0938–TBD) that is specific to the shortened enrollment form published in the **Federal Register** on November 18 (84 FR 63655) with a 60-day comment period and November 21, 2019 (84 FR 64319) with a burden correction. The shortened form has been made available for public review/comment outside of the rulemaking process since it is not tied to any of the provisions proposed in this rule, and it would not be subject to the effective date of the subsequent, final rule.

b. Plan Burden

Although not effective until January 1, 2021, section 17006 of the Cures Act amends the Act by allowing ESRD beneficiaries, without exception, to enroll in an MA plan. Consequently, OACT has incorporated an increase in ESRD enrollment in the Medicare Trust Fund baseline due to the legislation. The increases cover the plans' required revenue or submitted bid amounts, both medical (benefit) and administrative (non-benefit). The non-benefit expense portion of the bids include direct administrative expenses, indirect administrative expenses, gain and loss margins, marketing, and other items such as the net cost of private re-insurance as well as insurer fees. These non-benefit expenses generally make up a sizeable portion of the bid (about 16 percent for the 2020 bids).

Consequently, the expected increase to the plan for administering additional enrollments, due to additional ESRD beneficiaries enrolling in MA plans, has already been included in the currently approved burden estimates; therefore, this provision, which simply codifies the existing requirement, is not expected to have further impact beyond what is currently approved by OMB.

9. ICRs Regarding Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

The following proposed changes will be submitted to OMB for approval under control number 0938–0763 (CMS–R–262). Subject to renewal, the control number is currently set to expire on April 30, 2022.

As described in section V.G. of this proposed rule, the proposed new paragraphs at § 423.128(d)(4) and (5) would require each Part D plan to implement a beneficiary RTBT no later than January 1, 2022. This tool would allow enrollees to view a plan-defined subset of the information included in the prescriber RTBT system which includes complete, accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives, and utilization management requirements). Plans would be able to use existing secure patient portals to fulfill this requirement, to develop a new portal, or to use a computer application.

As discussed in section V.G. of this proposed rule, we understand that most Part D plans have already created beneficiary portals that satisfy existing privacy and security requirements. Based on our conversations with the industry, we believe that the few plans that have yet to create a portal or web application will have one in place by January 1, 2022.

We estimate it would take 104 hours at $86.14/hr for a computer programmer to program this information into the beneficiary portal and an additional 52 hours to put this information into a user interface that is easily understood by enrollees. The time estimates are based on consultation with the healthcare industry and their IT staff to determine the time that it takes for minor changes in programming. Thus the cost of implementing RTBT is 44,928 hours (288 organizations * 56 hr) at a cost of 3,870,098 (44,928 hr * $86.14/hr).

We next estimate the cost of implementing the rewards and incentives program for use of RTBT. We will estimate three items: (A) Development of policies for the new program, (B) updating of systems, and (C) maintaining the program. We solicit stakeholder feedback on all our assumptions. We informally asked stakeholders who thought that only 10 percent of parent part D sponsors would create such a program. Since there are 288 Part D sponsors we expect 29 (288 * 0.10 or 10 percent) organizations to develop and use a reward and incentive program.

(A) Development of policy: We estimate that for each parent organization an operations manager and compliance officer working together at a combined hourly wage of $188.84/hr ($119.12/hr + $69.72/hr) would take a week of work, 40 hours, Therefore the aggregate impact is 1,160 hours (40 hr * 29 parent organizations) at a cost of $219,054 (1,160 hr * $188.84/hr).

(B) Since systems already exist to collect enrollee data, they will only have to be updated to collect data on use of RTBT and most of this work will be done when creating the RTBT. We therefore estimate, per parent organization, an extra week of work, 40 hours. Therefore, the aggregate impact is 1,160 hours (40 hr * 29 organizations) at a cost of $99,922 (1,160 hr * $86.14/hr).

(C) Since computer systems are doing most of the work we estimate that 2 administrative support workers each working at $36.04/hr will take 15 hours every month to maintain the program. Thus each parent organization will spend 360 hours per year (15 hr/month * 12 months * 2 workers). The aggregate impact is 10,440 hours (360 hr/organization * 29 organizations) at a cost of $376,258 (10,400 hr * $36.04/hr).

The aggregate impact for implementing the rewards and incentives for RTBT among those Part D sponsors who wish to do so is s 13,920 hours (1,160 hr + 1,160 hr + 10,440) at a cost of $695,234 ($219,054 + $99,922 + $376,258).

Since plans are in the best position to estimate their implementation costs, we seek comment on the accuracy of this burden estimate and on any measures that CMS can take to decrease the impact of this provision, while maintaining its utility for enrollees. In addition, because plans are in the best position to estimate any information collection implications, since they will be the stakeholders implementing this provision, we solicit comment on any other potential information collection implications.

While we are proposing to allow plans to offer rewards and incentives to enrollees who use the tool, we are not estimating burden for including rewards and incentives, since we are not requiring that plans provide rewards and incentives, and CMS does not have a means of calculating the costs and benefits of rewards and incentives at this time.

10. ICRs Regarding Establishing Pharmacy Performance Measure Reporting Requirements (§ 423.514)

The following proposed changes will be submitted to OMB for approval under control number 0938–0992 (CMS–10185). Subject to renewal, the control number is currently set to expire on December 31, 2021. It was last approved on December 7, 2018, and remains active.

We propose to amend § 423.514(a) by requiring that Part D sponsors report to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network pharmacy agreement. Given the growing practice of Part D sponsors measuring the performance of pharmacies that service Part D beneficiaries to determine the final cost of a drug under Part D, this reporting requirement will enable CMS to monitor the impact of these recoupment practices. This new Part D reporting requirements section would require plans to report their pharmacy performance measures' data. We estimate a collection of less than 15 data elements. As noted in the preamble, the Part D reporting requirements data elements, consistent with our proposed standard, would be specified through the standard non-rule PRA process after publication of the final rule, if this proposal is finalized. The standard non-rule process includes the publication of 60- and 30-day **Federal Register** notices.

Although the data elements will be made available for public review through the standard PRA process, we are providing the interested parties with

an initial projection of the potential burden estimates. In this regard there are currently 627 contracts that would be required to report their pharmacy performance measures' data. Part D sponsors currently report 6 sections of data to CMS in accordance with the Part D reporting requirements. Therefore, CMS does not expect compliance to these reporting requirements would result in additional start-up costs. Anticipated staff time spent performing these data collection would be 30 minutes for data analysts and/or IT analysts at a rate of $90.02/hr. We would require this information to be reported at the plan level once annually. Reporting at the plan level would generate 5,234 responses since there are currently 5,234 plans. In aggregate, we estimate an annual plan sponsor burden of 2,617 hours (5,234 plans * 1 report/year * 0.5 hr/report) at a cost of $235,582 (2,617 hr * $90.02/hr). We are soliciting input from stakeholders on the accuracy of these estimates and on any measures that CMS can take to decrease the burden of this provision.

11. ICRs Regarding Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2430)

MSA Enrollment

The proposed changes affecting MSA enrollment will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267). Subject to renewal, the control number is currently set to expire on December 31, 2021.

As discussed in section V.I.4. of this proposed rule, CMS is proposing to amend § 422.2440 to provide for the application of a deductible factor to the MLR calculation for MA MSA contracts that receive a credibility adjustment. The proposed deductible factor would serve as a multiplier on the credibility factor. The application of the proposed deductible factor would increase the MLRs of MSA contracts that receive this adjustment.

We believe that the proposed change to the MLR calculation for MSAs could potentially cause the number of enrollees in MSA plans to increase relative to enrollment projections under the current regulations. For this impact estimate, we make the following assumptions. If the proposed changes take effect, we assume:

- Enrollment in MSAs will double over the first 3 years that the proposed change is in effect. We believe 3 years is a reasonable time frame for the enrollment changes resulting from this policy to be phased in. We project that enrollment will double in order to avoid potentially understating the cost for the proposal. Our estimate is based on the largest potential change in enrollment that we could reasonably anticipate. We acknowledge that the proposed change could have no impact on enrollment.
- Relative to projections in the baseline, MSA enrollment will be 33.33 percent higher in contract year (CY) 2021 (increasing from 7,435 to 9,913), 66.67 percent higher in 2022 (increasing from 7,812 to 13,020), and 100 percent higher in CY 2023 (increasing from 8,179 to 16,358) to CY 2030 (increasing from 10,354 to 20,708).
- Half of the new enrollees in MA MSA plans would otherwise have been enrolled in other types of MA plans, and half would otherwise have been enrolled in FFS Medicare. We did not have a basis for assuming that migration to MSAs would predominantly be from FFS Medicare or from non-MSA MA plans.

The process for enrolling in an MA plan is the same regardless of whether that plan is an MSA or a non-MSA. Therefore, we assume that the burden to enroll in an MSA plan and a non-MSA plan is the same. Therefore, the increased burden related to changes in MSA enrollment is attributable only to the portion of potential new MSA enrollees who would be expected to enroll in FFS Medicare if the proposal is not finalized. The cost burden of this proposal is summarized in Table 20.

a. Beneficiary Burden

For beneficiaries, the burden associated with the expected increase in MSA enrollment as a consequence of our proposal would be related to the effort it takes for a beneficiary to complete an enrollment request. It takes 0.5 hours at $24.98/hr for a beneficiary to complete an enrollment form. We assume no burden increase for the estimated fifty percent of additional MSA enrollees who would otherwise be enrolled in a non-MSA MA plan. For 2021, the burden for all beneficiaries is estimated at approximately 620 hours (2,478/2 beneficiaries * 0.5 hr) at a cost of $15,488 (620 hr * $24.98/hr). For 2022, the burden for all beneficiaries is estimated at approximately 1,302 hours (5,208/2 beneficiaries * 0.5 hr) at a cost of $32,524 (1,302 hr * $24.98/hr). For 2023, the burden for all beneficiaries is estimated at approximately 2,045 hours (8,179/2 beneficiaries * 0.5 hr) at a cost of $51,084 (2,045 hr * $24.98/hr).

The average burden per year is 1,322 hours ([620 + 1,302 + 2,045]/3) at an average cost of $33,032 ([$15,488 + $32,254 + $51,084]/3).

b. MA Organization Estimate

There are currently four MA organizations offering MSA plans in 2020. We project that this number will double in 2021 as a result of the proposed change. We therefore estimate that the proposed change would result in approximately 2,478 total additional enrollments in MSAs in 2021, or 310 additional enrollments per organization (2,478 individuals/8 organizations); in 2022, 5,308 total additional enrollments in MSAs, or 664 additional enrollments per organization (5,308 individuals/8 organizations); and in 2023, and 8,531 total additional enrollments, or 1,066 additional enrollments per organization (8,531 individuals/8 organizations).

The MA organization must give the beneficiary prompt written notice of acceptance or denial of the enrollment request in a format specified by CMS that meets the requirements set forth in this section. The burden associated with each organization providing the beneficiary prompt written notice, performed by an automated system, is estimated at 1 minute per application processed. We estimate that it will take 1 minute at $74.00/hr for a business operations specialist to electronically generate and submit a notice to convey the enrollment or disenrollment decision for each beneficiary. As noted previously, we anticipate that half of the new enrollees in MSAs will already be enrolled in other MA plans, meaning the current burden estimate for their enrollment is already accounted for in the currently approved collection. For 2021, the burden to complete the notices for the other half of new MSA enrollees (that is, the new enrollees who would otherwise enroll in FFS Medicare) is approximately 21 hours (2,478/2 notices * 1 min/60) at a cost of $1,554 (21 hr * $74.00/hr) or $1.25 per notice ($1,554/1,239 notices) or $194.25 per organization ($1,554/8 MA organizations). For 2022, the burden to complete the notices for the half of new MSA enrollees who would otherwise enroll in FFS Medicare is approximately 43 hours (5,208/2 notices * 1 min/60) at a cost of $3,182 (43 hr * $74.00/hr) or $1.22 per notice ($3,182/2,604 notices) or $397.75 per organization ($3,182/8 MA organizations). For 2023, the burden is approximately 68 hours (8,179/2 notices * 1 min/60) at a cost of $5,032 (68 hr * $74.00/hr) or $1.23 per notice ($5,032/4,090 notices) or $629.00 per organization ($5,032/8 MA organizations).

The average burden per year is 44 hours ([21 hr + 43 hr + 68 hr]/3) at an average cost of $3,256 ([$1,554 + $3,182 + $5,032]/3).

The burden associated with electronic submission of enrollment information to CMS is estimated at 1 minute at $74.00/hr for a business operations specialist to submit the enrollment information to CMS during the open enrollment period. The total burden for 2021 is approximately 21 hours (2,478/2 submissions × 1 min/60) at a cost of $1,554 (21 hr * $74.00/hr) or $1.25 per submission ($1,554/1,239 submissions) or $194.25 per organization ($1,554/8 MA organizations). For 2022, the total burden is approximately 43 hours (5,208/2 submissions × 1 min/60) at a cost of $3,182 (43 hr * $74.00/hr) or $1.22 per submission ($3,182/2,604 submission) or $397.75 per organization ($3,182/8 MA organizations). For 2023, the total burden is approximately 68 hours (8,179/2 submissions * 1 min/60) at a cost of $5,032 (68 hr * $74.00/hr) or $1.23 per submission ($5,032/4,090 submissions) or $629.00 per organization ($5,032/8 MA organizations).

The average burden per year is 44 hours ([21 hr + 43 hr + 68 hr]/3) at an average cost of $3,256 ([$1,554 + $3,182 + $5,032]/3).

Additionally, MA organizations will have to retain a copy of the notice in the beneficiary's records. The burden associated with this task is estimated at 5 minutes at $36.04/hr for an office and administrative support worker to perform record retention for the additional MA MSA enrollees. In aggregate, we estimate an annual burden for 2021 of 103 hours (2,478/2 beneficiaries * 5 min/60) at a cost of approximately $3,712 (103 hr * $36.04/hr) or $473 per organization ($3,784/8 MA organizations). For 2022, we estimate an aggregated annual burden of 217 hours (5,208/2 beneficiaries * 5 min/60) at a cost of approximately $7,821 (217 hr * $36.04/hr) or $978 per organization ($7,821/8 MA organizations). For 2023, we estimate an aggregated annual burden of 341 hours (8,179/2 beneficiaries * 5 min/60) at a cost of approximately $12,290 (341 hr * $36.04/hr) or $1,536.25 per organization ($12,290/8 MA organizations).

The average burden per year is 220 hours ([103 hr + 217 hr + 341 hr]/3) at an average cost of $7,941 ([$3,712 + $7,821 + $12,290]/3).

MLR Calculation

The proposed changes affecting the MLR calculation will be submitted to OMB for approval under control number 0938–1232 (CMS–10476). Subject to renewal, the control number is currently set to expire on December 31, 2021.

MA organizations will need to spend additional time calculating the MLRs for MSA contracts in order to apply the proposed deductible factor. We estimate that for each of the 8 MA organizations that we anticipate will offer MSA contracts in 2021 and in each year through 2030, it will take an actuary approximately 5 minutes at a wage of $111.78/hr to calculate the deductible factor for the contract. In aggregate, we estimate an annual burden of 0.6667 hours (5 min/60 * 8 MA organizations) at a cost of approximately $75 (0.6667 hr × $111.78/hr) or approximately $9 per organization ($111.78/hr * 0.0833 hr).

The average (in fact, actual) burden per year is 0.6667 hr at a cost of $75. For 2021, we estimate a total burden for all MA organizations resulting from this proposed provision to be 145.6667 hours (21 hr + 21 hr + 103 hr + 0.6667 hr) at a cost of $6,895 ($1,554 + $1,554 + $3,712 + $75). Per organization, we estimate an annual burden of approximately 18.2 hours (145.6667 hr/8 MA organizations) at a cost of $861.88 ($6,895/8 organizations). For beneficiaries we estimate a total annual burden of 620 hours at a cost of $15,488 and a per beneficiary burden of 30 minutes at $12.50.

For 2022, we estimate a total burden for all MA organizations resulting from this proposed provision to be 303.6667 hours (43 hr + 43 hr + 217 hr + 0.6667 hr) at a cost of $14,260 ($3,182 + $3,182 + $7,821 + $75). Per organization, we estimate an annual burden of approximately 38 hours (303.6667 hr/8 MA organizations) at a cost of $1,782.50 ($14,260/8 organizations). For beneficiaries we estimate a total annual burden of 620 hours at a cost of $15,488 and a per beneficiary burden of 30 minutes at $12.50.

For 2023, we estimate a total burden for all MA organizations resulting from this proposed provision to be 477.6667 hours (68 hr + 68 hr + 341 hr + 0.6667 hr) at a cost of $22,429 ($5,032 + $5,032 + $12,290 + $75). Per organization, we estimate an annual burden of approximately 60 hours (477 hr/8 MA organizations) at a cost of $2,803.63 ($22,429/8 organizations). For beneficiaries we estimate a total annual burden of 620 hours at a cost of $15,488 and a per beneficiary burden of 30 minutes at $12.50.

Summary

TABLE 20: IMPACT OF MSA/MLR BY SUBJECT

Respondents	Subject	2021	2022	2023	3-year average
Beneficiaries	Enrollment request	$15,488 (620 hours)	$32,524 (1,302 hours)	$51,084 (2,045 hours)	$33,032 (1,322 hours)
MA organizations	Notice to beneficiaries	$1,554 (21 hours)	$3,182 (43 hours)	$5,032 (68 hours)	$3,256 (44 hours)
MA organizations	Submission to CMS	$1,554 (21 hours)	$3,182 (43 hours)	$5,032 (68 hours)	$3,256 (44 hours)
MA organizations	Record retention	$3,712 (103 hours)	$7,821 (217 hours)	$12,290 (341 hours)	$7,941 (220 hours)
MA organizations	Calculation of deductible factor	$75 (0.6667 hours)	$75 (0.6667 hours)	$75 (0.6667 hours)	$75 (0.6667 hours)
MA ORGANIZATIONS TOTAL		$6,895 (145.6667 hours)	$14,260 (303.6667 hours)	$22,429 (477.6667 hours)	$14,528 (309 hours)

12. ICRs Regarding Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38)

The following proposed changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267) for Part C and 0938–0964 (CMS–10141) for Part D.

We are proposing to codify certain Part C (at § 422.62(b)(4) through (25)) and Part D (at § 423.38(c)(11) through (32)) SEPs for exceptional circumstances currently set out in sub-regulatory guidance that MA organizations and Part D plan sponsors have implemented and are currently following. We are also proposing to establish two new additional SEPs for exceptional circumstances: The SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer.

We do not believe the proposed changes will adversely impact individuals requesting enrollment in Medicare health or drug plans, the plans themselves, or their current enrollees. Similarly, we do not believe the proposed changes would have any impact on the Medicare Trust Fund.

Our proposal represents the codification of existing policy on SEPs for exceptional circumstances that has been specified in sub-regulatory guidance for quite some time, as well as the addition of the two aforementioned new SEPs for exceptional circumstances. MA organizations and Part D plan sponsors are currently assessing applicants' eligibility for election periods as part of existing enrollment processes; therefore, no additional burden is anticipated from this proposal. However, because a burden estimate for determining an applicant's eligibility for an election period has not previously been submitted to OMB, due to inadvertent oversight, we are seeking their approval under the aforementioned OMB control numbers.

We estimate it would take approximately 5 minutes (0.0833 hr) at $74.00/hr for a business operations specialist to determine an applicant's eligibility for an election period.

The burden for all MA organizations is estimated at 142,497 hours (1,710,650 beneficiary SEP elections * 0.0833 hr) at a cost of $10,544,778 (142,497.1450 hr * $74.00/hr) or 58,258 per parent organization ($10,544,778/181 MA parent organizations).

The burden for all Part D parent organizations is estimated at 155,564 hours (1,867,519 beneficiary SEP elections * 0.0833 hr) at a cost of $11,511,736 (155,564 hr * $74.00/hr) or $217,203 per Part D parent organization ($11,511,736/53 Part D parent organization).

13. ICRs Regarding Service Delivery Request Processes Under PACE (§§ 460.104 and 460.121)

The following proposed changes will be submitted to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number is currently set to expire on June 30, 2020.

Under new § 460.121(i)(2) discussed in section VII.A. of this proposed rule, we are proposing to require that PACE organizations provide written notification to participants whenever they extend the processing timeframe for service delivery requests. Based on our experience with PACE audits during 2017 and 2018, during which time we reviewed all PACE organizations in operation in that period, we found a total of 34,146 service delivery requests. The average PACE total enrollment during that period was 40,040. Thus the average number of service delivery requests per 1,000 enrollees was 852.8 (34,146/40.040). Based on the same audit experience and data collected, we further estimate that:

- Approximately 12 percent of all service delivery requests currently received are extended,
- Of those 852.8 service delivery requests currently received, 80 percent are approved, while 20 percent are denied.

Based on our proposed amendments to this section, we believe that half of the requests that are approved (that is, 50 percent of the 80 percent of requests not denied) could be approved in full by an IDT member at the time the request is made. Because those approval decisions could be made immediately (and therefore would not need to be fully processed as service delivery requests), the extension notification would not apply to those service delivery requests.

The proposed requirement of written notification for requests that are extended would apply to:

- The 2.4 percent of service delivery requests which are extended and subsequently denied (20 percent of service delivery requests are denied * 12 percent of service delivery requests are extended), and
- The 4.8 percent of service delivery requests that are approved and not routine (that is, a member of the IDT cannot approve the service delivery request in full at the time the request is made) and are extended (80 percent not denied * 50 percent not routine * 12 percent extended).

Thus the proposal would apply to 7.2 percent (2.4 percent denied and extended and 4.8 percent approved, not routine, and extended) of all service delivery requests. Based on OACT estimates, the average projected PACE enrollment for 2021–2023 is 47,680.

We also estimate, based on our audit experience, that to prepare and issue notification of the extension to a participant or the designated representative would take the IDT approximately 1 hour.

Consequently, the total annual burden of this request is 2,928 hours (852.8 requests per 1,000 * 47,680 projected enrollment for 2021–2023 * 7.2 percent of requests that require extensions * 1 hour to process each service delivery request extension) at a cost of $164,612 (2,928 hr * $56.22/hr for a Master's-level Social Worker (MSW) to process them).

Section 460.104(d)(2) currently states the requirements for processing service delivery requests (that is, requests from participants or their designated representatives to initiate, eliminate, or continue a service). We are proposing to move these requirements to new § 460.121 and modify the requirements to reduce burden on PACE organizations while ensuring appropriate participant protections are in place. We are proposing to require PACE organizations to notify participants or their designated representatives when they take an extension when processing a service delivery request. We expect most PACE organizations would develop a template letter to notify the appropriate parties in these situations. We are also clarifying requirements regarding the content of denial notifications following the determination of a service delivery request, which would require PACE organizations to update their denial notification letter templates.

For the development and revision of the extension notification and denial notification, we estimate a burden of 2 hours at $69.72/hr for a compliance officer to create and revise the materials. We estimate a one-time burden of 262 hours (131 PACE organizations * 2 hr) at a cost of $18,267 (262 hr * $69.72/hr).

14. ICRs Regarding Appeals Requirements Under PACE (§§ 460.122 and 460.124)

The following proposed changes will be submitted to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number is currently set to expire on June 30, 2020.

Section 460.122 currently states the requirements for implementing an appeals process in PACE. We are proposing to modify the appeals section to increase clarity for organizations and ensure appropriate participant protections are in place. We are proposing to require PACE organizations to develop and distribute written materials that would explain the PACE requirements to the third party reviewers that are responsible for making appeal determinations. Additionally, we are proposing to increase requirements around what appeal decision notifications must include, which we expect would require PACE organizations to revise their current appeal notification materials.

For the development and distribution of materials to the third party reviewer, we estimate it would take 4 hours at $69.72/hr for a quality officer at each PACE organization to create and distribute these materials (3 hr to create and 1 hr to distribute). For the revision of the written appeal notices, we estimate it would take 1 hour at $69.72/hr for a quality officer at each PACE organization to revise the current notices.

In aggregate, we estimate a one-time burden of 655 hours [131 PACE organizations * (4 hr + 1 hr)] at a cost of $45,667 (655 hr * $69.72/hr).

15. ICRs Regarding Documenting and Tracking the Provision of Services Under PACE (§ 460.98)

The following proposed changes will be submitted to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number is currently set to expire on June 30, 2020.

As discussed in section VII.E. of this proposed rule, we are proposing to amend § 460.98 in part to require PACE organizations to document, track and monitor the provision of services across all care settings, regardless of whether services are formally incorporated into a participant's plan of care. The burden associated with this requirement would consist of the time and effort required for PACE organizations to develop and implement procedures and to perform the required documentation, tracking and monitoring.

We estimate a one-time burden of 50 hours at $50.90/hr for technical staff at each PACE organization to develop the necessary procedures and written materials. We estimate a one-time burden of 6,550 hours (131 PACE organizations * 50 hr) at a cost of $333,395 (6,550 hr * $50.90/hr) for the first year. Since PACE organizations are already required to document all services furnished in the medical record in accordance with § 460.210(b)(2), we believe that by adding the requirement to track and monitor the provision of those services, the one-time burden of 50 hours would be a reasonable estimate on how long it would take to ensure procedures were developed.

We also estimate this provision would result in increased ongoing costs to PACE organizations. To estimate the increased burden, we use the following assumptions about the documentation, tracking, and monitoring of services, based on our experience monitoring and auditing PACE organizations.

As organizations are already required to document services furnished in the participant's medical record, PACE organizations would need to devote time to tracking and monitoring the provision of services in order to ensure services are being provided. We therefore estimate a burden of 50 hours at $50.90/hr for technical staff to complete these activities, including, when warranted, revision of the aforementioned program procedures and monitoring measures. We estimate a total aggregate annual cost at $333,395 (131 PACE organizations * 50 hr * $50.90/hr). This annual cost combined with the one-time cost of $333,395 for developing written procedures and materials would total $666,790 for the first year of implementation.

16. ICRs Regarding Documentation in Medical Records Under PACE (§ 460.210)

The following proposed changes will be submitted to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number is currently set to expire on June 30, 2020.

Section 460.210 currently includes the requirements relating to medical records for PACE participants. This includes the minimum content of participant medical records. As discussed in section VII.F. of this proposed rule, we are proposing to require PACE organizations to maintain additional documentation in the medical record, including documentation of all recommendations for services made by employees or contractors of the PACE organization, the reasons for not approving or providing any service recommended by an employee or contractor of the PACE organization, and original documentation of any written communication the PACE organization receives relating to the care, health or safety of a participant. While PACE organizations would not have to develop new systems for maintaining this documentation, we expect that they would have to revise their policies and procedures and re-train staff on the new requirements. We believe that a compliance officer or quality officer would be responsible for ensuring the necessary materials are updated and that staff are trained. For revising materials and training staff, we estimate a one-time burden of 10 hours at $69.72/hr for technical staff to revise materials and lead training. Therefore, the one-time burden to implement this provision is 1,310 hours (131 PACE organizations * 10 hr) at a cost of $91,333 (1,310 hr * $69.72/hr).

We also estimate this provision would result in increased ongoing costs to PACE organizations. To estimate the increased burden, we use the following assumptions about medical record documentation. These assumptions are based on our experience monitoring and auditing PACE organizations' compliance with clinical processing requirements and medical record documentation.

As discussed previously, we proposed requiring three additional types of documentation to be included within a participant's medical record. Specifically, the documentation of recommendations made by employees and/or contractors, the reasons for not approving or providing a recommended service, and the original documentation of any written communication the PACE organization receives relating to the care, health or safety of a participant. Of these new requirements, we estimate that the requirement to maintain original documentation of any written communication the PACE organization receives relating to the care, health or safety of a participant, in any format, would not create a large burden, as organizations would only be required to save the already created documentation within a medical record. Therefore, we estimate that the total burden for part of the provision would be 5 hours per PACE organization or 655 total hours (5 hr/organization * 131 organizations).

We also proposed to require a PACE organization to document recommendations for services from employees or contractors of the PACE organization, including specialists. Furthermore, we are proposing to require PACE organizations to document the reasons a service recommended by an employee or contractor of the PACE organization is not approved or provided. We considered several factors when determining the estimated burden associated with these provisions. First, PACE organizations are already required under § 460.104(b)(1) to document the

rationale for not providing services following initial comprehensive assessments in the development of the care plan; therefore this provision would only apply to services recommended following the initial care plan development. Second, PACE organizations would only have to document the rationale under proposed § 460.210(b)(5) when the PACE organization does not approve or provide a recommended service, so there would be no additional burden in situations where the PACE organization approves or provides a recommended service. Considering these two factors, we determined that each PACE organization would have to spend approximately 51 hours (approximately 1 hr per week) to implement this part of the regulation. Therefore, we estimate a total of 56 hours per organization (51 hr + 5 hr), or a total of 7,336 hours (56 hr * 131 organizations).

Additionally, any IDT occupation may be involved in the documentation of this rationale depending on the type of service being recommended. Therefore, to determine the cost associated with this provision, we took the cost of one hour of wages for the full IDT ($838.36) and divided it by the 11 occupations included in the IDT (see Table 21) to determine an average wage of $76.21 ($838.36/11). We believe this is the most accurate estimate as it would be unlikely all occupations were working at the same time, and we are unable to estimate how much any one occupation would work over a different occupation.

TABLE 21—WAGES FOR IDT STAFF MEMBERS *

Occupation title	Occupation code	Mean hourly wage with fringe benefits and overhead ($/hr)
Primary Care Provider	29–1069	196.04
Registered Nurse	29–1141	72.60
Home Care Coordinator (often a RN)	29–1141	72.60
Physical Therapist	29–1123	85.46
Occupational Therapist	29–1122	82.08
Masters of Social Work	21–1022	56.22
Recreational Therapist	29–1125	48.68
Dietician	29–1031	58.86
Driver	53–3022	32.10
Personal Care Attendant	31–1011	24.36
PACE Center Manager	11–9111	109.36
Total		838.36
Average IDT Cost Per Hour		76.21

*See section IX.A. of this proposed rule.

We estimate the total cost of this provision to be $559,077 (7,336 hr * $76.21/hr).

17. ICRs Regarding PACE Participant Rights: Contact Information and Access Requirements (§ 460.112)

The following proposed changes will be submitted to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number is currently set to expire on June 30, 2020.

Section 460.112 currently includes the specific rights to which PACE participants are entitled. As discussed in section VII.G. of this proposed rule, we are proposing to modify the participant rights to include three new distinct rights, specifically, the participant's right to have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines, the right to call 1–800–MEDICARE with questions or concerns regarding the program, and the right to receive necessary care in all care settings, up to and including placement in a long-term care facility when the PACE organization can no longer maintain the participant safely in the community. The PACE organization is currently required to provide a copy of this set of participant rights to participants at the time of enrollment, and they are required to post a copy of the rights in the center. Under these proposals, the PACE organization would be required to revise the current participant rights to account for the three new requirements.

We estimate it would take 2 hours at $69.72/hr for technical staff to update the participant rights information included in the enrollment information and post the new participant rights in the center. In aggregate, we estimate a one-time burden of 262 hr (131 PACE organizations * 2 hr) at a cost of $18,267 (262 hr * $69.72/hr).

18. ICRs Regarding Stipulated Decisions in Part C (§ 422.562)

In order to permit OMHA adjudicators to more efficiently issue decisions where there is no longer any material issue in dispute, we are proposing to include MA organizations in the definition of ''contractors'' as that definition relates to stipulated decisions issued by ALJs and attorney adjudicators under § 405.1038. We are scoring this impact as negligible for several reasons. The total number of favorable decisions in MA for contract year 2018, the most recent year for which we have complete appeals data, was 578. The number of these overturned denials that were stipulated decisions is not currently quantifiable as it is not data that existing appeals systems are equipped to track, and ALJs do not track this data on their own.

We consulted with OMHA for its opinion on stipulated decisions, and OMHA estimated that the number of contractors submitting oral or written statements in an ALJ hearing or attorney adjudicator review was in the single digits because plans prefer an alternate, informal approach that removes the claim from the appeals process altogether: Requesting that the beneficiary withdraw their appeal and resubmit their claim for payment. The

reason for this preference is currently speculative at best.

CMS estimates that while this proposal would positively impact beneficiaries both in receipt of their items or services, and afford beneficiaries due process protections in a formalized stipulated decisions process, the number of beneficiaries that would be affected is minimal. Despite this estimation of negligible impact, CMS is proposing inclusion of this provision to promote regulatory uniformity in their approach to stipulate decisions as far as Medicare contractors are concerned. The submission of a written or oral statement seeking a stipulated decision is an ICR that is associated with an administrative action pertaining to specific individuals or entities (5 CFR 1320.4(a)(2) and (c)). Consequently, the burden for preparing and filing the oral or written statement for use in the appeal is exempt from the requirements and collection burden estimates of the PRA.

C. Summary of Proposed Information Collection Requirements and Associated Estimates

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TABLE 22: ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS[1, 2, 3]

Provision	Regulatory Citation	OMB Control Number	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost in 1st year ($)	Total Cost in Subsequent Years ($)
SNPs	§ 422.101	0938-1296	MOC submission	273	273	6	1,638	73	118,919	118,919
SNPs	§ 422.101	0938-1296	MOC revision	11	11	4	44	73	3,194	3,194
SNPs	§ 422.101	0938-1296	MOC resubmission	14	14	3	42	73	3,049	3,049
SNPs	§ 422.101(f)(1)(iv)	0938-1296	Face-to-face	734	734	4	2,936	73	213,154	213,154
D-SNP Look-Alikes	§ 422.514 (e)	0938-0753	Transition enrollees, 1st year	62	62	2	124	74	9,176	
D-SNP Look-Alikes	§ 422.514 (e)	0938-0753	Transition enrollees, subsequent years	5	5	2	10	74		740
D-SNP Look-Alikes	§ 422.514 (e)	0938-0753	Filling out enrollment form	1,808	1,808	1	904	25	22,582	
D-SNP Look-Alikes	§ 422.514 (e)	0938-0753	Filling out enrollment form	146	146	1	73	25		1,824
DMP	§ 423.153	0938-0964	Upload model notices	79	79	5	395	86	34,025	
DMP	§ 423.153	0938-0964	Disclosure to CMS	79	158	0	3	51	134	134
DMP	§ 423.153	0938-0964	Creating DMP (those without DMPs)	79	79	80	6,320	476	3,008,573	
DMP	§ 423.100	0938-0964	Send model notices	288	8,677	0	1,446	51	73,601	73,601
DMP	§ 423.100	0938-0964	Revise model notices	288	288	1	288	51	14,659	

Provision	Regulatory Citation	OMB Control Number	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost in 1st year ($)	Total Cost in Subsequent Years ($)
DMP	§ 423.100	0938-0964	Disclosure to CMS (newly identified PARBs)	288	18,268	0	305	51	15,525	15,525
DMP	§ 423.100	0938-0964	Case management	288	18,268	1	18,268	542	9,909,659	9,909,659
DMP	§ 423.100	0938-0964	Case management	288	158	1	158	542		85,636
MTMP	§ 423.153	0938-1154	Mailing ARBs CMR	288	8,421			1	7,747	7,747
MTMP	§ 423.153	0938-1154	Targeting ARBs for MTM	288	8,421	1	5,614	119	667,505	667,505
MTMP	§ 423.153	0938-1154	Safe disposal page in CMR	288	2,181,675			0	21,817	21,817
MTMP	§ 423.153	0938-1154	Safe disposal page in TMR	288	325,997			0	3,570	3,570
Education on Addiction	§ 423.128	0938-0964	Update systems	288	288	2	576	86	49,617	
Education on Addiction	§ 423.128	0938-0964	Create materials	288	288	2	576	119	68,486	
Fraud & Abuse Pt C & D	§§422.503(b)(4)(vi)(G)(3) and 422.504(b)(4)(vi)(G)(3)	0938-TBD and 0938-1262	Report fraud and abuse	668	668	247	164,996	91	14,975,037	
Fraud & Abuse Pt C & D	§§422.503(b)(4)(vi)(G)(3) and 422.504(b)(4)(vi)(G)(3)	0938-TBD and 0938-1262	Report fraud and abuse	668	668	156	104,208	91		9,457,918
ESRD	§§422.50 and 422.52	0938-0753	Enrollment	59,000	59,000	1	29,500	25	736,910	736,910
RTBT	§ 423.128	0938-0763	Policy development	29	29	40	1,160	189	219,054	

Provision	Regulatory Citation	OMB Control Number	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost in 1st year ($)	Total Cost in Subsequent Years ($)
RTBT	§ 423.128	0938-0763	Updating systems	29	29	40	1,160	86	99,922	
RTBT	§ 423.128	0938-0763	Program maintenance	29	29	360	10,440	36	376,258	376,258
RTBT	§ 423.128	0938-0763	Implementing RTBT	288	288	156	44,928	86	3,870,098	
Pharmacy performance	§ 423.514	0938-0992	Pharmacy performance	5,234	5,234	1	2,617	90	235,582	235,582
MSA MLR	§§ 422.2420, 422.2440, and 422.2430	0938-1252	Calculation of the deductible factor	3	3		1	112	75	75
MSA MLR	§§ 422.2420, 422.2440, and 422.2430	0938-0753	Filling out enrollment forms	3	3		1,322		33,032	33,032
MSA MLR	§§ 422.2420, 422.2440, and 422.2430	0938-0753	Notify enrollees	3	3		44		3,256	3,256
MSA MLR	§§ 422.2420, 422.2440, and 422.2430	0938-0753	Submit to CMS	3	3		44		3,256	3,256
MSA MLR	§§ 422.2420, 422.2440, and 422.2430	0938-0753	Archive	3	3		220		7,941	7,941
SEP Part C	§ 422.62	0938-0753	Filling out enrollment forms	181	1,710,650	0	142,497	74	10,544,778	10,544,778
SEP Part D	§ 422.38	0938-0964	Filling out enrollment forms	53	1,867,519	0	155,564	74	11,511,736	11,511,736
PACE	§§ 460.104 and 460.121	0938-0790	Extension notification	131	2,928	1	2,928	56	164,612	164,612

Provision	Regulatory Citation	OMB Control Number	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost in 1st year ($)	Total Cost in Subsequent Years ($)
PACE	§ 460.104(d)(2)	0938-0790	Update for extension notification	131	131	2	262	70	18,267	-
PACE	§ 460.104(d)(2)	0938-0790	Update appeal notices	131	131	5	655	70	45,667	
PACE	§460.104(d)(2)	0938-0790	Develop written materials for tracking	131	131	50	6,550	51	333,395	
PACE	§460.104(d)(2)	0938-0790	Tracking services	131	131	50	6,550	51	333,395	333,395
PACE	§§ 460.104 and 460.121	0938-0790	Medical record documentation training	131	131	10	1,310	70	91,333	
PACE	460.104(d)(2)	0938-0790	Medical record documentation	131	131	56	7,336	76	559,077	559,077
PACE	§ 460.104(d)(2)	0938-0790	Update for patients' rights	131	131	2	262	70	18,267	
TOTAL	*Varies*	*Varies*	*Varies*	6,190	6,180,284		724,273	*Varies*	58,425,940	45,093,900
Subtotal Enrollees							328,538		22,816,006	22,795,248
Subtotal Plans							395,735		35,609,934	22,298,652

NOTES:

[1] The hours and dollars for MSA MLR are averages over three years. Consequently hours * wages/hr does not exactly equal total cost. Since the number of respondents varied per year, "*Varies*" was placed in that cell.

[2] N/A refers to non-labor mailing cost.

[3] Total row contains "*Varies*" because, for example, respondents could be plans, cohorts of plan, enrollees, cohorts of enrollees, or parent organizations.

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D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections previously discussed, please visit CMS's website at: *https://www.cms.gov/RegulationsandGuidance/Legislation/PaperworkReductionActof1995/PRAListing.html,* or call the Reports Clearance Office at (410) 786–1326.

We invite public comments on these proposed information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule and identify the rule (CMS–4190–P) and where applicable the ICR's CFR citation, CMS ID number, and OMB control number.

See the **DATES** and **ADDRESSES** sections of this proposed rule for further information.

X. Regulatory Impact Analysis

A. Statement of Need

This rule proposes several mandatory regulatory changes stemming from federal laws related to the Part C and D programs—including the BBA of 2018, the SUPPORT Act, and the Cures Act. The statutory need for these policies is clear. However, this rule contains various other proposals that are discretionary policies, including enhancements to the Programs of All-Inclusive Care for the Elderly (PACE) requirements, hence we provide economic justification for some of these noteworthy provisions in the following paragraphs.

We estimate that the proposed Star Ratings provisions would result in an overall net savings for the Medicare Trust Fund. There are two proposed changes that may impact a contract's Star Rating: (1) We propose to increase measure weights for patient experience/complaints and access measures from two to four to further emphasize the patient voice, and (2) we propose the use of Tukey outlier deletion, which is a standard statistical methodology for removing outliers, to increase the stability and predictability of the non-CAHPS measure cut points. The proposed increased weight reflects CMS's commitment to put patients first and to empower patients to work with their doctors to make health care decisions that are best for them. Since more outliers tend to be at the low end of the distribution (worse performers), directly removing outliers causes some shifting downward in overall Star Ratings. The increased measure weights for patient experience/complaints and access revision is assumed to be a cost to the Medicare Trust Fund given the ratings for these measures tend to be higher relative to other measures, and the Tukey outlier deletion is assumed to be a saver to the Medicare Trust Fund since directly removing outliers results in a shift downward in ratings. The aggregate savings to the Medicare Trust Fund over 2024–2030 is $4.9 billion.

Based on industry feedback over the course of several years, and our experiences auditing PACE organizations, we are proposing to modify certain PACE requirements to enhance stakeholders' understanding of our requirements and reduce administrative burden. Stakeholders have suggested that the existing processes for addressing service delivery requests is burdensome for PACE organizations, and can delay participants' access to services. We are proposing several changes to the PACE regulations to streamline these processes while ensuring that important participant protections remain intact. We believe these changes will save PACE organizations approximately $20 million a year.

B. Overall Impact

We examined the impact of this proposed 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), Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking (August 13, 2002), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (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).

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

This proposed rule affects MA and PACE organizations and Part D sponsors (North American Industry Classification System (NAICS) category 524114) with a minimum threshold for small business size of $41.5 million (*http://www.sba.gov/content/small-business-size-standards*). This proposed rule additionally affects hospitals (NAICS subsector 622), a variety of provider categories, including physicians and specialists (NAICS subsector 621), pharmacy related businesses (NAICS code 3254), and information technology (IT) services (54141).

To clarify the flow of payments between these entities and the federal government, note that MA organizations and Part D sponsors submit bids (that is, proposed plan designs and projections of the revenue needed to provide those benefits, divided into three categories—basic benefits, supplemental benefits, and Part D drug benefits) in June 2020 for operation in contract year 2021. These bids project utilization of services from and payments to hospitals, providers, and staff as well as the cost of plan administration and profits. These bids in turn determine the payments from the Medicare Trust Fund to the MA organizations and Part D Sponsors that pay providers and other stakeholders for their provision of covered benefits to enrollees. Consequently, our analysis will focus on those plan types that submit bids (primarily MA organizations and Part D Sponsors) for which we have complete data. We will supplement this data with internal CMS financial data, which we have for all plan types.

There are various types of Medicare health plans, including MA organizations and their plans, Part D sponsors and Part D plans (PDPs), demonstration plans, section 1876 cost plans, PDPs, and PACE organizations. We use the term ''Medicare health plan'' as a general term referring to any of these plan types just listed. By examining records from the most recent year for which we have complete data, 2019, we determined, that to the nearest 10 percent, approximately 40 percent of all Medicare health plan organizations are not-for-profit. Note that the 40 percent applies to all Medicare health plans. Some important subcategories have different proportions. For example, coordinated care plans are 30 percent not-for-profit, PACE plans are 90 percent not-for-profit, and PDPs are about 50 percent not-for-profit. The attribute ''small business'' only applies to for-profit entities and, for insurers such as MA plans and Part D sponsors, refers to for-profit entities whose receipts are under $41.5 million. While we have financial information on MA plans and Part D sponsors, we do not

have total receipts. We have used proposed bids and payments as a proxy for receipts.

Executive Order 13272 requires that HHS thoroughly review rules to assess and take appropriate account of their potential impact on small business, small governmental jurisdictions, and small organizations (as mandated by the RFA).

If a proposed rule may have a significant economic impact on a substantial number of small entities, then the proposed rule must discuss steps taken, including alternatives, to minimize burden on small entities. The RFA does not define the terms ''significant economic impact'' or ''substantial number.'' The Small Business Administration (SBA) [109] advises that this absence of statutory specificity allows what is ''significant'' or ''substantial'' to vary, depending on the problem that is to be addressed in the rulemaking, the rule's requirements, and the preliminary assessment of the rule's impact. To ensure that a broad range of impacts are fully considered in the analysis, we consider ''substantial number'' to mean 3–5 percent or more of the affected small entities within an identified industry.

The 1984 HHS Handbook, On Developing Low Burden and Low Cost Regulatory Proposals, set forth the following definitional narrative for the term ''significant economic impact'' and is still applicable: A rule has a significant economic impact on the small entities it affects, if it significantly affects their total costs or revenues. If the economic impact is expected to be similar for all affected small entities and those entities have similar costs and revenues, then an average impact can be calculated. If the average annual impact on small entities is 3 to 5 percent or more, then we consider the rule has a significant economic impact on small entities.

While a significant number (more than 30 percent) of the organizations affected by this proposed rule are not-for-profit organizations, the impact is not significant. As shown in Table 41, the net impact of this rule is an annualized savings of $5.8 million a year resulting from a $28.8 million savings versus a $23 million cost. This annualized cost is significantly below 3–5 percent of the net receipts of all plans.

While this rule has significant impact on the Medicare Trust Fund and United States Treasury as detailed in this Regulatory Impact Analysis, neither of these entities are ''small businesses.'' Consequently, this impact is not discussed in this section.

We next discuss the impact on hospitals, physician and other provider practices, pharmacy related businesses, and IT services.

As discussed in sections IX and X of this proposed rule, many of the provisions require system updates necessitating programming and other IT services. More specifically, the following provisions have PRA impacts involving IT services: Beneficiary RTBT, Fraud and Abuse, PACE, ESRD, SEP Part C/D, DMP, and Education on Addiction. Based on estimates in section IX, the combined cost of IT services is approximately $50 million, which is significantly below the 3–5 percent threshold that would trigger further discussion. Furthermore, this $50 million represents payments for services rendered not a burden per se.

The provisions of this rule primarily affect the responsibility of MA organizations and Part D sponsors to furnish services. This means that services that were formerly paid for out-of-pocket or by other insurances are now paid for by the Part C and D programs. Therefore, the provisions of this proposed rule do not impose specific burdens on hospitals or providers.

For example, the various provisions affecting enrollment (ESRD, SEP Part C/D, MSA) require that the Medicare Trust Fund pay for services provided to those who enroll. In some cases, this change is limited to who pays. In other cases, surgeries and other procedures that would not have been purchased are not being furnished to enrollees. However, these services are being paid for; they are not independent burdens.

Unlike the previous mentioned stakeholders (where there was no impact), we do expect pharmacy-related businesses to be impacted by this rule. For example, the DMP provisions will likely reduce prescription utilization for the targeted population. As a result, the Medicare Trust Fund will have lower expenditures. Similarly, pharmacies and drug manufacturers will have lower sales volumes. The provisions for mandatory DMPs and the provisions to include beneficiaries with a history of opioid overdose as PARBs will involve prescribers in case management. We believe network providers are typically contractually obligated to participate in utilization review activities by plan sponsors, and non-network providers are not. If any pharmacy limitations are implemented as a result, this will involve network pharmacies, which we believe are also contractually obligated to participate in drug utilization review activities. Additionally, we estimate approximately 40,000 beneficiaries will be identified as PARBs, which constitutes approximately 0.08 percent of Part D enrollees.

As detailed in this Regulatory Impact Analysis, the DMP provisions will reduce spending by about $7.7 million a year and, as just indicated, likely reduce revenue to pharmacies and manufacturers. The MTMP provisions will bring in an extra $0.7 million per year due to increased requirements. The preferred specialty tier for Part D could have the effect that brand manufacturers may have to lower their prices and/or offer better rebates for placement on the preferred specialty tier relative to other brands or the potential for more generic drug or biosimilar/interchangeable biological product alternatives. Similarly, this provision may encourage generic manufacturers to develop more generic drug or biosimilar/interchangeable biological product alternatives at competitive prices (that is, relative to pricing changes by brand manufacturers). The Office of the Actuary (OACT) could not estimate this effect of the preferred specialty tier for Part D. The combined total impacts to pharmacies is estimated at under $25 million a year (the big drivers being the reduced drug utilization due to DMP, the DMP case management, and the MTMP requirements). This is significantly less than the 3–5 percent of total revenue of pharmacies required to trigger further discussion.

Consequently, the Secretary has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities, and we have met the requirements of Executive Order 13271 and the RFA. In addition, section 1102(b) of the Act requires us to prepare a regulatory analysis for any rule under title XVIII, title XIX, or part B of title XI of the Act that may have significant impact on the operations of a substantial number of small rural hospitals. We are not preparing an analysis for section 1102(b) of the Act because the Secretary certifies that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. This proposed rule is not

[109] The Regulatory Flexibility Act An Implementation Guide for Federal Agencies, pages 17–19. Issued by SBA's Office of Advocacy, and accessible at *www.sba.gov/advo.*

anticipated to have an unfunded effect on state, local, or tribal governments, in the aggregate, or on the private sector of $154 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this proposed rule does not impose any substantial costs on state or local governments, preempt state law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this proposed rule, then we should estimate the cost associated with regulatory review. There are currently 795 contracts (which includes MA, MA–PD, and PDP contracts), 55 state Medicaid Agencies, and 300 Medicaid MCOs. We also expect a variety of other organizations to review (for example, consumer advocacy groups, major Pharmacy Benefit Managers). Each organization will designate one person to review the rule. A reasonable maximal number is 2,000 total reviewers. We note that other assumptions are possible.

Using the BLS wage information for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this proposed rule is $109.36 per hour, including fringe benefits and overhead costs (*http://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 100 hours for each person to review this proposed rule. For each entity that reviews the rule, the estimated cost is therefore $10,936 (100 hours * $109.36). Therefore, we estimate that the maximum total cost of reviewing this proposed rule is $21 million ($10,936 * 2,000 reviewers). We expect that many reviewers will not review the entire rule but just the sections that are relevant to them. If each person on average reviews 10 percent of the rule, then the cost would be $2 million.

Note that this analysis assumed one reader per contract. Some alternatives include assuming one reader per parent organization. Using parent organizations instead of contracts will reduce the number of reviewers. However, we believe it is likely that review will be performed by contract. The argument for this is that a parent organization might have local reviewers assessing potential region-specific effects from this proposed rule.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by OMB.

C. Anticipated Effects

Many of the provisions of this proposed rule have no impact either because they are technical provisions or are provisions that codify existing guidance. Other provisions have an impact although it cannot be quantified or whose estimated impact is zero. Throughout the preamble, we have noted when provisions have no impact. Additionally, this Regulatory Impact Analysis discusses several provisions with either zero impact or impact that cannot be quantified. The remaining provisions are estimated in section IX of this proposed rule and in this Regulatory Impact Analysis. Where appropriate, when a group of provisions have both paperwork and non-paperwork impact, this Regulatory Impact Analysis cross-references impacts from section IX of this proposed rule in order to arrive at total impact. Additionally, this Regulatory Impact Analysis provides pre-statutory impact of several provisions whose additional current impact is zero because their impact has already been included in the appropriate baselines. For further discussion of what is estimated in this Regulatory Impact Analysis, see Table 10 and the discussion afterwards.

1. Beneficiaries With History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)

This provision would require that CMS identify beneficiaries enrolled in Medicare Part D with a history of opioid-related overdose (as defined by the Secretary) and include such individuals as PARBs for prescription drug abuse under the Part D sponsor's drug management program. We projected a list of approximately 18,000 beneficiaries that met the criteria for this provision between July 2017 and June 2018, but did not meet other criteria for classification as a potential at-risk beneficiary. Under this proposal, this population is projected to (1) increase the population of enrollees requiring case management by plan sponsors (see section IX.B.3. of this proposed rule), and (2) reduce Part D drug cost.

We evaluated their Prescription Drug Event (PDE) data for the same July 2017 and June 2018 period to determine the effects of this provision. After examining the PDE data, we found that these beneficiaries had an average gross drug cost per beneficiary per year of $9,675. Because this amount is high relative to the typical Part D spending and because they do not meet other at-risk criteria, it is likely that many of these beneficiaries have conditions that require expensive specialty medications. These drugs have complex clinical criteria that are difficult to alter through utilization management. Accordingly, we have assumed that 5 percent of their Part D drug cost would be reduced through additional plan management. Our estimated fiscal year federal savings rounded to the nearest million are shown in Table 23. Since these drugs would not be purchased as a result of efficient case management, they represent reduction in goods consumed and are true savings to the Medicare Trust Fund.

TABLE 23—ESTIMATED BENEFITS TO THE MEDICARE TRUST FUND OF THE INCLUSION OF ADDITIONAL AT-RISK BENEFICIARIES

Fiscal Year	Fiscal year ($ in millions)										Total 2021–2030 Impact ($ in millions)
	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2021–2030
Estimated Impact	$6	$8	$8	$8	$8	$8	$8	$8	$8	$8	$75

Table 24 summarizes the aggregate impact of the changes to DMPs. It reflects all the estimates related to DMPs in section IX of this proposed rule (which incur costs) and the savings due to reduction in drug costs discussed in this Regulatory Impact Analysis.

TABLE 24—SUMMARY OF DMP IMPACTS BY PROVISION

[Millions $]

	1st yr savings	1st year cost	Annual savings 2nd–10th year	Annual cost 2nd–10th year	Total 10-year savings	Total 10-year cost
Mandatory DMP Case Management (COI)				0.1		0.8
DMP Paperwork (COI)		3.1		0.1		3.9
DMP Overdose Case Management (COI)		9.9		10.0		99.9
DMP Drug savings	5.8		7.7		75.4	
Total					75.4	104.6
Net Impact (Cost) over 10 years						29.2

2. Automatic Escalation to External Review Under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries (§§ 423.153, 423.590, and 423.600)

As stated in the preamble, starting in 2022, the SUPPORT Act requires automatic escalation of drug management program appeals to the independent outside entity contracted with the Secretary for review and resolution. We are proposing rules to codify that provision.

To estimate the impact of this proposal, we first determined how many Part D sponsors had implemented drug management plans. As of July 9, 2019, we found that 60 Part D sponsors had implemented drug management plans. Next, we estimated of the number of CARA-appeals per 1,000 enrollees and the percentage of plan denials related to CARA. To do this, we contacted nine Part D sponsors and asked how many CARA related appeals they had received from January 1, 2019 through July 31, 2019.

Of those nine, eight plans responded they had have not received any CARA appeals. One Part D sponsor responded to say they had received CARA related appeals. That plan reported a rate of 0.014 CARA related appeals per 1000 enrollees. This accounted for 0.08 percent of plan denials. Since there are about 28,600 appeals per year, therefore there are only about 23 cases (0.08 percent * 28,600) affected by this provision. Since most IRE cases are judged by a physician at a wage of $202.46 and typically an IRE will take at most 1 hour to review most cases, the total burden is about $4,656.58 (23 cases * $202.46 * 1 hour) or $0.0 million.

3. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

We are unable to determine the overall impact of implementing sections 2008 and 6063 of the SUPPORT Act because we do not have adequate data to support an estimate of the potential costs and savings. While we do have access to estimates of overall Medicare Part D opioid spending, sections 2008 and 6063 of the SUPPORT ACT are not expected to impact all Part D opioid prescriptions, nor do we expect that they would impact all pharmacies that dispense those medications. For example, section 2008 of the SUPPORT Act requires Part D plan sponsors to report to CMS any payment suspension pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o) of the Act. In addition, section 6063 of the SUPPORT Act requires MA organizations and Part D plan sponsors to report information on the investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier related to fraud, and other actions taken by the plan related to inappropriate prescribing of opioids. In both cases, these provisions would directly impact a percentage of all opioid prescriptions written by doctors and dispensed by pharmacies. While we believe there may be savings generated through actions taken by Part D plan sponsors that will conduct their own due diligence from the reporting and sharing of administrative actions between CMS, MA organizations and Medicare Part D plan sponsors (including MA organizations offering MA–PD plans), as well as additional law enforcement actions, we cannot estimate the impact at this time. We welcome comment and suggestions for data that could be relied upon for this purpose.

4. Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

CMS is proposing to codify requirements under section 17006 of the Cures Act that, effective for the plan year beginning January 1, 2021, would remove the prohibition for beneficiaries with ESRD from enrolling in an MA plan. Since CMS is proposing to codify existing statute, there would be no impact to program expenditures. In order to estimate the impact of requirements under section 17006 of the Cures Act, a pre-statute baseline was used to estimate the impacts.

There are two primary assumptions that contribute to the regulatory impact analysis for this provision: (1) The increased number of beneficiaries with ESRD who choose to enroll in an MA health plan; and (2) The cost differential between MA and FFS for those enrollees with ESRD.

We are expecting that there will be an influx of beneficiaries switching from FFS to MA beginning on January 1, 2021 due to the provision. In 2019, there were 532,000 enrollees in ESRD status with Medicare Part A benefits as shown in the Medicare Enrollment Projections tables of the 2020 Medicare Advantage Rate Announcement. Of these, 401,000 enrollees were in the FFS program, which results in 131,000 in Private Health Plans. This equates to a private health penetration rate of about 25 percent. Absent the ESRD enrollment provision of the Cures Act, we project that ESRD enrollment in Private Health plans will grow to 144,000 in 2021, representing about 26 percent of the projected 2021 total ESRD population of 559,000. Based on an analysis by OACT, ESRD enrollment in MA plans is expected to increase by 83,000 due to the Cures Act provision. This increase is assumed to be phased in over 6 years,

with half of the beneficiaries (41,500) enrolling during 2021.

Next, we determine the cost differential of the projected ESRD enrollees that are new to MA in 2021 due to the Cures Act. The cost differential between MA and FFS ESRD enrollees is attributed to the adjustment to MA risk scores for differences in diagnosis coding between MA and FFS beneficiaries. The Coding Intensity (Annual) was derived by examining historical risk score data and computing the differences between MA and FFS risk scores. Demographic differences (age, gender factors) for enrollees have been separated and removed from risk score comparisons so that the final differences are considered health status differences.

Table 25 shows the cost for codifying section 17006 of the Cures Act, removing the prohibition for ESRD beneficiaries to enroll in MA plans. The United States Per Capita Cost (USPCC) amounts for Part A and Part B can be found in the 2020 Medicare Advantage Rate Announcement. The Gross Costs (before backing out the Part B premium portion) is calculated by multiplying the Additional MA ESRD Enrollment by the ESRD–USPCC rates, which are on a per member per month basis, multiplied by 12 (the number of months in a year) multiplied by the Composite Coding Intensity. The Net Cost is calculated by multiplying the Gross Costs by the Net of Part B Premium amount which averages between 85.6% and 84.9% from 2021–2030. The Net Costs range from $23 million in Calendar Year 2021 to $440 million in CY 2030.

TABLE 25: ESTIMATED COST PER YEAR (MILLIONS) TO THE MEDICARE TRUST FUND FOR REMOVING THE PROHIBITION FOR ESRD BENEFICIARIES TO ENROLL IN MA PLANS

Contract Year	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Additional MA ESRD Enrollment:	41,500	62,250	73,317	78,850	81,617	83,000	83,000	83,000	83,000	83,000
USPCC Pt A FFS ($):	3,206	3,328	3,447	3,562	3,681	3,801	3,924	4,052	4,184	4,320
USPCC Pt B FFS ($):	4,900	5,109	5,329	5,573	6,383	6,662	6,953	7,257	7,574	7,905
USPCC FFS ($):	8,106	8,437	8,776	9,136	10,063	10,462	10,877	11,309	11,758	12,225
Coding Intensity (Annual):	0.65%	0.80%	0.79%	0.63%	0.46%	0.30%	0.14%	0.14%	0.13%	0.13%
Coding Intensity (Composite):	0.65%	1.46%	2.26%	2.90%	3.38%	3.69%	3.84%	3.98%	4.12%	4.25%
Gross Cost ($ millions):	26	92	174	251	333	384	416	448	482	518
Net of Part B Premium:	85.60%	85.60%	85.50%	85.40%	85.30%	85.20%	85.00%	84.90%	84.90%	84.90%
Net Cost ($ millions):	23	79	149	214	284	327	353	381	410	440

Because these increases are already included in the baseline, they are not included in Table 41, nor do they contribute to the monetized table calculations (Table 40). However, notes to Table 41 and observations in the conclusion do mention this impact.

5. Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries (§ 422.322) and Exclusion of Kidney Acquisition Costs From Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306)

Section 17006(b) of the Cures Act amended section 1853(k) and (n) of the Act to exclude standardized costs for kidney acquisitions from MA benchmarks starting in 2021. As such, CMS is proposing to codify these requirements so that, effective for the contract year beginning January 1, 2021, MA organizations will no longer be responsible for costs for organ acquisitions for kidney transplants for

their beneficiaries. Removing these costs from the MA benchmarks will decrease the amounts paid to the plans from the Medicare trust funds. Instead, as required by statute, CMS proposes to require that Medicare FFS cover the kidney acquisition costs for MA beneficiaries, effective 2021.

Since the budget baseline has reflected this change from the publication of the Cures Act, there is no additional impact of the proposed codification of this change to the computation of rates. To estimate the impact of the statute when published we used a pre-statute baseline. This impact of the statute will therefore not be included in Table 41 or Table 40, which deal with impacts of current provision.

Our analysis in the next section shows that: (1) FFS coverage of kidney acquisition costs for MA beneficiaries results in net costs to the Medicare Trust Funds ranging from $212 million in 2021 to $981 million in 2030; (2) Excluding kidney acquisition costs from MA benchmarks results in net savings estimated to range from $594 million in 2021 to $1,346 million in 2030. In addition, we anticipate no change in plan, provider, or beneficiary burden for these provisions. Plan burden would not be impacted by the change in their payment rate. Provider burden will not be impacted because they continue to bill for kidney acquisition regardless of whether they receive payment from FFS Medicare or MA organizations. Finally, beneficiaries would not be impacted by the change in the source of payment for the acquisition of the organ.

Next, we describe the steps used to calculate the savings associated with excluding kidney acquisition costs from MA benchmarks as well as the costs associated with requiring FFS coverage of kidney acquisition costs for MA beneficiaries.

First, we examined the FFS cost of kidney acquisition coverage. We calculate the expected costs to the FFS program for covering kidney acquisitions from the MA population starting in 2021. The costs for these services are expected to be lower than the amount that is expected to be excluded from the MA benchmarks for two reasons.

1. The MA penetration rate for ESRD enrollees is lower than for the non-ESRD enrollees. This means that a higher percentage of beneficiaries with ESRD are in FFS than in MA, so there will likely be fewer kidney transplants in MA versus FFS. However, this enrollment difference will likely lessen as ESRD enrollees are permitted to enroll in MA plans beginning in 2021.

2. The kidney transplant incidence rate for MA ESRD enrollees has historically been much lower than the kidney transplant incidence rate for FFS ESRD enrollees. We suspect that this is due to MA ESRD enrollees being in dialysis status for a shorter duration than FFS enrollees. Again, we believe that this difference (between MA and FFS) in the kidney transplant incidence rate will decrease over time as more ESRD beneficiaries enroll in MA plans.

The kidney transplant incidence rate is computed by dividing the number of kidney transplants by the ESRD enrollment separately for the MA and FFS programs. As shown in table 26, the FFS kidney transplant incidence rate has historically often been more than three times the MA rate.

TABLE 26: MEDICARE FFS AND MA KIDNEY TRANSPLANTS (2013-2017)

	2013	2014	2015	2016	2017
Number of Kidney Transplants FFS:	13,964	13,866	14,400	15,191	15,346
ESRD Enrollment FFS (000's):	385	390	394	401	402
Transplant Incidence FFS:	3.6%	3.6%	3.7%	3.8%	3.8%
Number of Kidney Transplants MA:	929	1,015	957	1,137	1,382
ESRD Enrollment MA (000's):	69	78	89	96	108
Transplant Incidence MA:	1.3%	1.3%	1.1%	1.2%	1.3%

As mentioned, we expect that as a greater portion of enrollees with ESRD will join MA plans, starting in 2021, the difference in the kidney transplant incidence rate between MA and FFS will begin to lessen, as shown in table 27. The total number of MA and FFS kidney transplants are expected to grow by 3 percent per year which is based on the 2013–2017 historical growth rate. That rate is higher than the average increase in MA and FFS ESRD enrollment of 2 percent for 2013–2017. Since the kidney transplant growth is projected to be higher than the ESRD enrollment growth, we expect the kidney transplant incidence rate to increase over time.

TABLE 27: MEDICARE FFS AND MA KIDNEY TRANSPLANTS (2018-2030)

	2018	2019	2020	2021	2022	2023	2024
Number of Kidney Transplants MA & FFS:	17,230	17,747	18,279	18,828	19,392	19,974	20,573
Kidney Transplant Incidence FFS:	3.9%	4.0%	4.0%	4.2%	4.3%	4.4%	4.3%
Kidney Transplant Incidence MA:	1.4%	1.4%	1.4%	1.6%	1.8%	2.0%	2.2%
ESRD Enrollment FFS (000's):	401	401	408	373	358	353	352
ESRD Enrollment MA (000's):	120	131	137	186	213	231	242
	2025	2026	2027	2028	2029	2030	
Number of Kidney Transplants MA & FFS:	21,191	21,826	22,481	23,155	23,850	24,566	
Kidney Transplant Incidence FFS:	4.3%	4.2%	4.2%	4.1%	4.1%	4.0%	
Kidney Transplant Incidence MA:	2.4%	2.6%	2.8%	3.0%	3.2%	3.4%	
ESRD Enrollment FFS (000's):	354	358	364	369	374	379	
ESRD Enrollment MA (000's):	250	256	261	266	270	274	

We then calculate the average kidney acquisition costs using FFS claims data from CMS data systems. The average kidney acquisition costs ranged from $69,000 in 2013 to $83,000 in 2017, which equates to an annual growth rate of 4.7 percent. This percentage was used to estimate average kidney acquisition costs during the projection period of 2018 to 2030.

The gross costs to the FFS program for covering MA kidney acquisition costs are computed by multiplying the MA transplant incidence rate by the number of MA ESRD enrollees multiplied by the average kidney acquisition cost. This computation was completed for the years 2021–2030. The gross costs, as found in the Table 28, range from $298 million in 2021 to $1,384 million in 2030. Again, we apply the government share of the gross savings factors as well as the Part B premium factors to compute the net costs to the Medicare Trust Funds. These factors are the same as those used to calculate the savings for excluding kidney acquisition costs from the MA benchmarks. The net costs to the Medicare Trust Funds after applying these factors are expected range from $212 million in 2021 to $981 million in 2030.

TABLE 28: COSTS TO THE FFS PROGRAM FOR COVERING MA KIDNEY ACQUISITION COSTS

	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Kidney Transplant Incidence MA:	1.6%	1.8%	2.0%	2.2%	2.4%	2.6%	2.8%	3.0%	3.2%	3.4%
ESRD Enrollment MA (000's):	186	213	231	242	250	256	261	266	270	274
Avg Kidney Acq Costs ($'s):	99,146	103,804	108,680	113,786	119,131	124,728	130,587	136,722	143,145	149,870
Gross Costs ($Millions):	297.9	401.3	503.0	605.7	713.5	828.7	950.2	1,082.5	1,226.1	1,383.7
Avg Gov't Share of Gross Savings:	83.0%	83.0%	83.0%	83.1%	83.2%	83.2%	83.2%	83.4%	83.4%	83.4%
Net of Part B Premium:	85.6%	85.6%	85.5%	85.4%	85.3%	85.2%	85.0%	84.9%	84.9%	84.9%
Net Costs ($Millions):	211.7	284.9	357.0	429.5	506.0	587.1	672.3	766.5	869.1	980.8

Next, we examined the MA cost of kidney acquisition coverage. We used data based on the kidney acquisition costs for the FFS beneficiaries to compute the portion of the MA benchmark that has been attributed to kidney acquisition costs. In order to compute the amount that the MA health plans have been reimbursed for these costs in the past, we tabulated Medicare's share of kidney acquisition costs and the number of Medicare discharges from the Medicare Cost Reports (Form CMS–2552–10) for certified kidney transplant centers. The kidney acquisition costs were computed for the years 2013–2017 (the latest data that was available at the time of this study) using information from the Medicare Cost Reports for FFS beneficiaries at the county-level. The county level per member per month (PMPM) costs are derived by summing the kidney acquisition costs for each county and dividing these amounts by the county specific Medicare FFS enrollment. These annual costs per member are then divided by 12 in order to compute the PMPM's.

Next, we examine the historical kidney acquisition cost PMPM trend for the years 2013–2017 to project these costs for the years 2018–2030. In aggregate, the kidney acquisition PMPM costs grew at an average rate of 6.4 percent during 2013–2017. This trend is used to estimate these costs for the 2018–2030 period.

To calculate the gross savings to the Medicare Trust Funds, we multiply the projected MA enrollment by the annual per member kidney acquisition costs. We then apply two additional factors to the gross savings in order to compute the net savings to the Medicare Trust Funds:

1. Average government share of gross savings. Government expenditures are the sum of bids and rebates. Rebates are the portion of the difference between the MA benchmarks and MA bids that the health plans use to pay for additional supplemental benefits or reductions in enrollee cost sharing. The government retains the remaining difference between MA benchmarks and MA bids. We estimate that bids will be reduced by 50 percent of the total reduction in benchmarks.

2. Net of Part B premium. Medicare enrollees, not the Trust Funds, are responsible for approximately 25 percent of their Part B costs.

The government share of gross savings factors are expected to be between 83.0 percent and 83.4 percent during the period 2021–2030. The net of Part B premium factors are expected to be 85.6 percent and 84.9 percent during that same period. The results can be found in table 29. The net savings due to excluding kidney acquisition costs from MA benchmarks is estimated to range from $594 million in 2021 to $1,346 million in 2030.

TABLE 29: MEDICARE FFS KIDNEY ACQUISITION COST DATA

	2013	2014	2015	2016	2017	2018	2019	2020		
Kidney Acq Costs (PMPM):	1.72	1.82	1.95	2.08	2.20	2.34	2.49	2.65		
	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Kidney Acq Costs (PMPM):	2.82	3.00	3.20	3.40	3.62	3.85	4.10	4.36	4.64	4.94
Medicare Advantage Enrollment Projection (000's):	24,690	25,624	26,508	27,380	28,237	29,070	29,861	30,607	31,313	32,035
Gross Savings ($Millions):	836.2	923.5	1,016.6	1,117.4	1,226.3	1,343.4	1,468.4	1,601.7	1,743.7	1,898.4
Average government share of Gross Savings:	83.0%	83.0%	83.0%	83.1%	83.2%	83.2%	83.2%	83.4%	83.4%	83.4%
Net of Part B Premium:	85.6%	85.6%	85.5%	85.4%	85.3%	85.2%	85.0%	84.9%	84.9%	84.9%
Net Savings ($Millions):	594.1	655.7	721.5	792.3	869.5	951.7	1,038.9	1,134.1	1,235.9	1,345.6

6. Reinsurance Exceptions (§ 422.3)

It is difficult to determine whether there would be a cost or savings impact to this proposal. The use of reinsurance or other arrangements permitted by the proposal is a choice for MA organizations, which they can exercise if they believe it is in their business interests to purchase. While purchasing reinsurance coverage has a cost associated with it, the use of reinsurance provides financial protection that may generate offsetting savings to the MA organization, or reduce their risk. We therefore are unable to quantitatively estimate the impacts of this provision. We solicit stakeholder comment on (i) how this provision may be used, (ii) likely costs and savings, and (iii) other related impacts.

7. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)

We are proposing some measure updates and technical clarifications as well as the methodology changes (concerning outliers and the weight of patient experience/complaints and access measures). These measure updates and technical clarifications are routine and do not have an impact on the highest ratings of contracts (that is,

overall rating for MA–PDs, Part C summary rating for MA-only contracts, and Part D summary rating for PDPs). These type of routine changes have historically had very little or no impact on the highest ratings. Hence, there will be no, or negligible, impact on the Medicare Trust Fund from the routine changes.

We are also proposing to clarify some of the current rules around assigning Quality Bonus Payment (QBP) ratings and to codify the rules around assigning QBP ratings for new contracts under existing parent organizations. We are not proposing any changes to our current QBP policies, so there will be no impact on the Medicare Trust Fund from these proposals.

The cost impacts due to the Star Ratings updates are calculated by quantifying the difference in the MA organization's final Star Rating with the proposed rule and without the proposed rule. There are two ways that our proposed rule could cause a contract's Star Rating to change: (1) We propose in this rule to increase measure weights for patient experience/complaints and access measures from two to four, and (2) we propose the use of Tukey outlier deletion, which is a standard statistical methodology for removing outliers. There are assumed to be Medicare Trust Fund impacts due to the Star Ratings changes associated with these two revisions to the methodology. The increased measure weights for patient experience/complaints and access revision is assumed to be a cost to the Medicare Trust Fund, as there are more contracts that would see their Star Ratings increase than decrease. The Tukey outlier deletion is assumed to be a saver to the Medicare Trust Fund, as more contracts would see their Star Ratings decrease rather than increase.

All impacts are considered transfers since no goods or services are increased or decreased.

The impact analysis for the Star Ratings updates takes into consideration the final quality ratings for those contracts that would have Star Ratings changes under this proposed rule. There are two ways that Star Ratings changes will impact the Medicare Trust Fund:

1. A Star Rating of 4.0 or higher will result in a QBP for the MA organization, which, in turn, leads to a higher benchmark. MA organizations that achieve an overall Star Rating of at least 4.0 qualify for a QBP that is capped at 5 percent (or 10 percent for certain counties).

2. The rebate share of the savings will be higher for those MA organizations that achieve a higher Star Rating. The rebate share of savings amounts to 50 percent for plans with a rating of 3.0 or fewer stars, 65 percent for plans with a rating of 3.5 or 4.0 stars, and 70 percent for plans with a rating of 4.5 or 5.0 stars.

In order to estimate the impact of the Star Ratings updates, the MA baseline assumptions are updated with the assumed Star Ratings changes described in this proposed rule. The MA baseline is completed using a complicated, internal CMS model. The main inputs into the MA baseline model include enrollment and expenditure projections. Enrollment projections are based on three cohorts of beneficiaries: (i) Dual-eligible beneficiaries, (ii) beneficiaries with employer-sponsored coverage, and (iii) all others, including individual-market enrollees. MA enrollment for all markets is projected by trending the growth in the penetration rates for the 2011 through 2018 base data. The key inputs for the expenditure projections include:

- United States Per Capita Cost (USPCC) growth rates.
- Adjustment to MA risk scores for differences in diagnosis coding between MA and fee-for-service beneficiaries.
- Quality bonus (county-specific).
- Phase-out of Indirect Medical Education (county-specific).

Projections are performed separately for payments from the Part A and Part B trust funds. Aggregate projected payments are calculated as the projected per capita cost times the projected enrollment. The Medicare Trust Fund impacts are calculated by taking the difference of the MA baseline with the Star Ratings changes and the original MA baseline.

The results are presented in Table 30. The last column of Table 29 presents net savings to the Medicare Trust Fund; in 2024 the savings is $368.1 million; this will grow over time reaching $999.4 million by 2030. The aggregate savings over 2024–2030 is $4.9 billion. Ordinary inflation is carved out of these estimates. The source for ordinary inflation is Table II.D1 of the 2019 Medicare Trustees report. It should be noted that there are inflationary factors that are used in the projected Star Ratings and are used in these estimates. The Star Ratings are assumed to inflate at a higher rate for the lower rated contracts than for the higher rated contracts. MA organizations with low Star Ratings have a better chance of improving their quality ratings than MA organizations that have already achieved a high Star Rating. For instance, a contract with a Star Rating of 4.5 has less room to increase its Star Rating than a contract with a Star Rating of 3.0.

There is a large projected reduction in the costs associated with the proposed increase in the weight of measures classified as patient experience/complaints and access measures in 2029. This is due to several contracts that are projected to achieve the required 4.0 Star Rating in 2029 and are eligible for the QBP at that time, even after this proposed rule is applied. This narrows the difference in costs between the proposed rule and the original baseline.

TABLE 30: CALCULATIONS OF NET SAVINGS PER YEAR TO THE MEDICARE TRUST FUND FOR STAR RATINGS UPDATES

Calendar Year	Cost of Increased Weight in Patient Experience/ Complaints and Access Measures ($ Millions)	Net Savings from Tukey Outlier Deletion ($ Millions)	Net Savings	Ordinary Inflation	Net Savings with Ordinary Inflation Carved Out ($ Millions)
2024	391.4	808.9	417.5	3.20%	368.1
2025	305.4	935.0	629.6	3.20%	537.9
2026	296.1	1,029.0	732.9	3.20%	606.7
2027	343.4	1,110.5	767.1	3.20%	615.3
2028	301.1	1,296.5	995.4	3.20%	773.7
2029	93.9	1,356.9	1,263.0	2.60%	956.8
2030	95.7	1,449.2	1,353.5	2.60%	999.4
Total 2024-2030					4857.9

8. Permitting a Second, ''Preferred'', Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

The proposed option for Part D sponsors to offer a second, ''preferred'' specialty tier has the potential to impact Part D drug costs in two ways. First, a Part D sponsor may have additional negotiating power with brand drug manufacturers by offering a preferential tier position relative to the current single specialty tier. Second, Part D sponsors may promote lower-cost biosimilar biological products on a preferred specialty tier. We consider each of these possibilities in the following discussion.

For a Part D sponsor to be able to negotiate better formulary position and lower beneficiary cost sharing for a particular specialty drug, there must be a substantial difference between the cost sharing on the preferred specialty tier and the higher cost sharing specialty tier. As the proposed regulation limits the maximum allowable cost sharing to the range of 25 to 33 percent, Part D sponsors must achieve this difference by lowering the cost sharing on the preferred specialty tier. Because of the high cost for specialty drugs and the structure of the Part D benefit, Part D enrollees and prescribers might not significantly alter their behavior in response to a five percent change in coinsurance, for example. A substantial reduction in the cost sharing for this tier would necessitate a substantial increase in cost sharing for other tiers to maintain an actuarially equivalent benefit, which may unfavorably change the competitive position of the Part D sponsor's plan offering. In particular, a plan that offers lower cost sharing on high-cost specialty drugs and higher cost sharing on conventional drugs would risk adverse selection from Part D enrollees.

In addition, allowing tiering exceptions between the preferred specialty tier and the higher cost sharing specialty tier creates a risk for the Part D sponsor that may exceed the benefit of being better able to negotiate with respect to brand drugs. A portion of the higher cost-sharing specialty drugs may be granted exceptions as the clinical criteria for such Part D drugs is complex and can lead to different prescriptions for beneficiaries with similar conditions. These Part D drugs are often more complicated chemically and apply to complex conditions, such as Rheumatoid Arthritis or Multiple Sclerosis. This added complexity requires greater specialized knowledge than a traditional small molecule drug would for denying an exception. This will be known to manufacturers, who will be less inclined to provide additional incentives for the preferred placement given that a significant amount of non-preferred use will limit any market share gains from their enhanced formulary position. Part D sponsors would also face additional liability from the difference in cost sharing between the preferred and the higher cost sharing specialty tier on prescriptions that are granted exceptions. This dynamic is what prevents Part D sponsors from placing specialty drugs on a non-preferred drug tier under current regulation.

Regarding savings from biosimilar biological products that could be promoted through a preferred specialty tier, some of the same previously discussed issues still apply. For example, Part D sponsors may expect a portion of a non-preferred reference biological product to be given an exception to the preferred tier for a biosimilar biological product if such biosimilar biological product is not licensed for all of the same indications as the reference biological product. Furthermore, the selection of these drugs is often largely determined by the behavior of the prescriber rather than the formulary status of the Part D sponsor. If the prescriber prefers the reference biological product, they are more likely to prescribe it rather than the biosimilar biological product, regardless of the formulary position. This is particularly true for specialty drugs, where the differences in total drug cost and in the cost-sharing provisions of the plan are not as extreme as the differences between conventional brand and generic drugs. Finally, it is worth noting that several large Part D sponsors do not currently promote biosimilar biological products. For example, Zarxio®, the biosimilar biological product to Neupogen®, is not included on the formulary for several large Part D plans.

Our conclusion is that the provisions of the proposed rule to allow Part D sponsors to structure their benefits with

a second, ''preferred'' specialty tier are unlikely to have a material impact on Part D costs. While it is possible that a small savings to the Part D program could result from the enhanced flexibility, particularly for MA–PD plans with greater prescriber integration, broad adoption of a second specialty tier is unlikely. Nevertheless, we believe there are reasons to propose a second specialty tier. As discussed in more detail in section V.F. of this proposed rule, stakeholders requesting this change have posited that it might lead to better rebates on certain Part D drugs and reduced costs for Part D enrollees and CMS. Most importantly, we are currently not aware of any major adverse effects that could result to Part D enrollees by allowing Part D sponsors to structure their benefits with a second, ''preferred'' specialty tier as proposed. For example, concern for undue financial burden on some Part D enrollees has prompted us to propose to retain the current maximum allowable cost sharing (that is, 25/33 percent, as discussed in more detail in section V.F. of this proposed rule). Additionally, we solicit comment regarding whether negative consequences to Part D enrollees could result from this proposal. If there were no foreseeable notable harms to Part D enrollees, it would seem reasonable to provide the requested flexibility to Part D sponsors and see if additional benefits do result, while monitoring implementation for adverse effects and responding as necessary.

As discussed in section V.F. of this proposed rule, improving Part D enrollee access to needed drugs, including lowering drug costs, are central goals for CMS. While this regulatory impact analysis assesses the potential impact this proposal will have on Part D drug costs, we also believe this proposal has the potential to impact patient access and lower drug costs more broadly by providing further incentives for manufacturers to develop generic drugs and biosimilar and interchangeable biological products. Even if notable savings for the Part D program were not to materialize, individual Part D enrollees might save a great deal on rebated Part D drugs. Or, the policy might result in the benefit of (1) more formulary choices, or (2) more choices at a lower cost than might have otherwise been the case. These, in turn, might lead to positive health outcomes with associated indirect savings to Part D enrollees or the government. We solicit comment on any other unforeseen benefits that might result. And, again, if we were to finalize this proposal, we would closely monitor for any adverse effects and take any necessary action including proposing warranted changes for future rulemaking.

9. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)

Regulatory Changes to Incurred Claims (§ 422.2420)

CMS is proposing to amend the regulation at § 422.2420(b)(2)(i) so that the incurred claims portion of the MLR numerator for an MA contract would include all amounts that an MA organization pays (including under capitation contracts) for covered services for all enrollees under the contract. Currently, § 422.2420(b)(2)(i) specifies that incurred claims include direct claims that an MA organization pays to providers (including under capitation contracts with physicians) for covered services provided to all enrollees under the contract.

CMS is proposing this amendment so that incurred claims in the MLR numerator will include expenditures for certain supplemental benefits that MA organizations are newly authorized to include in their PBPs as a result of recent policy and legislative changes. As explained in greater detail in sections II.A. and VI.F. of this proposed rule, recent subregulatory guidance and statutory changes have expanded the types of supplemental benefits that MA organizations may include in their PBPs. Beginning in 2020, pursuant to section 1852(a)(3)(D) of the Act, as amended by the BBA of 2018, MA organizations may provide SSBCI. SSBCI can include benefits that are not primarily health related, as long as the item or service has the reasonable expectation to improve or maintain the chronically ill enrollee's health or overall function. In addition, effective January 1, 2019, CMS's interpretation of ''primarily health related benefits,'' which is used as a criteria for supplemental benefits, has been changed to include services or items used to diagnose, compensate for physical impairments, ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization. To be considered ''primarily health related,'' a supplemental benefit must focus directly on an enrollee's health care needs and should be recommended by a licensed medical professional as part of a health care plan, but it need not be directly provided by one.

This impact analysis assumes that the proposed amendments to the MLR regulations would not impact MA enrollee benefits. In other words, the analysis assumes the proposed amendments would change the types of expenditures that could be included in the MLR numerator as incurred claims, but there would be no impact on the level or number of permissible enrollee benefits that MA plans elect to offer. We request comment on this assumption.

The requirements pertaining to the calculation and reporting of MA contracts' MLRs are presented in subpart X of 42 CFR part 422. MA organizations' contracts that do not meet the 85 percent minimum MLR requirement for a contract year are required to remit funds to CMS (§ 422.2410(b)). CMS collects remittances by deducting the amounts owed from MA organizations' monthly payments (§ 422.2470(c)). In the absence of statutory language directing CMS to return remitted funds to the Medicare Trust Fund, CMS transfers remittances to the Treasury. For purposes of this impact analysis, we assume contracts that have an MLR of less than 85 percent for one contract year do not continue to fail to meet the MLR requirement for an additional two consecutive contract years, which would result in imposition of enrollment sanctions, or for an additional four consecutive contract years, which would result in contract termination. This is consistent with our experience; although the MLR requirement has only been in effect for five contract years, to date, very few contracts have been subject to MLR-related enrollment sanctions, and only one contract has failed to meet the MLR requirement for more than three consecutive contract years. No contract has been terminated for failure to satisfy the MLR requirement for five consecutive contract years.

Total remittances for individual contract years can be substantial. Based on internal CMS data, the simple average of total remittances across all contracts for contract years 2014–2017 is $131 million. If we adjusted these payments to a 2017 level by trending for enrollment and per capita growth but carving out ordinary inflation, the average would be $139 million.

We anticipate that, if finalized, the proposed amendments to § 422.2420(b)(2)(i) would increase the numerator of the MLR because the incurred claims category would include certain expenditures that would not qualify for inclusion in the numerator under the current regulations. Specifically, under the proposed amendments to § 422.2420(b)(2)(i), incurred claims would include amounts

that an MA organization pays (including under capitation contracts) for covered services, regardless of whether payment is made to an individual or entity that is a provider as defined at § 422.2. We expect that this will cause some MA contracts which formerly did not satisfy the minimum MLR requirement of 85 percent to now meet or exceed it. For contracts that still fail to meet the 85 percent threshold, we anticipate that the amount of remittances would decrease. In other words, the proposed regulation would, if finalized, effectively result in a transfer of funds from the Treasury to the MA organizations through the Medicare Trust Fund. Amounts that MA organizations would remit and which the Treasury would receive under the current regulations would instead remain with the MA organizations, implying that MA organizations enjoy cost savings while the Treasury has a cost impact. The net impact on the Medicare Trust Fund would be zero, since there are no additional transfers from or to the Medicare Trust Fund; the only issue being whether the MA organizations retain additional funds or the Treasury receives fewer funds.

To estimate the amount of payments made for services that would be included in incurred claims under the proposed amendments to § 422.2420(b)(2)(i), we used data in the 2019 submitted bids to estimate the increase in the supplemental benefits category for the primarily health related benefits that MA organizations could include in their PBPs starting in 2019. This estimate is complicated by the fact that, in the absence of the proposed amendments to § 422.2420(b)(2)(i), some types of supplemental benefits that MA organizations could offer starting in 2019 could potentially meet the requirements at § 422.2430 to be quality improvement activities (QIAs) for MLR purposes, meaning expenditures for those benefits could be included in the MLR numerator. Based on the 2019 submitted bid information, a consideration of the types of benefits that MA organizations could offer under CMS's reinterpretation of the ''primarily health related'' definition, and the likelihood that some of these benefits would meet the requirements at § 422.2430(a) to be QIAs, we estimated a 52 percent increase in projected expenditures for the categories of ''primarily health related'' supplemental benefits that would not qualify for inclusion in the MLR numerator as ''incurred claims'' under current § 422.2420(b)(i) or as QIA under § 422.2430(a). The first year that the expanded interpretation of ''primarily health related benefits'' was implemented was 2019, and so the increase seen in these categories for 2019 is attributed to this reinterpretation. To date, MA organizations have only been able to include non-primarily health related SSBCI in their plan offerings for one year (that is, 2020). While early indications show that utilization for these benefits have been low, we expect the use of these benefits to grow over time as MA organizations become more familiar with them and have time to include them in future plan offerings. Due to the absence of credible data for SSBCI, the impact on future MLR remittances is currently unquantifiable. We will continue to track SSBCI information and adjust the forecasts as more information becomes available.

We then reevaluated the MLRs for those contracts that failed to meet the 85 percent MLR requirement for contract years 2014–2017 by revising the numerator calculation to incorporate the 52 percent increase in the previously listed benefits. The change in the numerator calculation resulted in several of the contracts passing the MLR requirement instead of failing. For contracts that would not have met the MLR requirement even with the revised numerator calculation, the amount of remittances decreased. The average decrease in remittance payments over the four year period (that is, 2014–2017) is estimated to be $25.8 million (in 2017 dollars).

In order to project the decrease in remittances for the years 2021–2030, the $25.8 million was increased using estimated enrollment and per capita increases based on Tables IV.C1 and IV.C3 of the 2019 Medicare Trustees Report, with ordinary inflation (Table II.D1 of the 2019 Medicare Trustees Report) carved out of the estimates.

The results are presented in Table 31, which shows that in the first year of the proposed provision, 2021, there would effectively be a transfer from the Treasury through the Medicare Trust Fund of $35.3 million to MA organizations. For computational transparency, the amounts in 2017–2020 are also shown representing amounts paid to the Treasury in those years. This transfer would take the form of a reduction in the remittance amounts withheld from MA capitated payments. This amount (that is, the amount of remittances *not* withheld from MA capitated payments if the proposal were finalized) is projected to grow over 10 years, resulting in a $56.4 million transfer from the Treasury through the Medicare Trust Fund to MA organizations in 2030. The total transfer from the Treasury to MA organizations over 10 years is $455 million. There is $0 impact on the Medicare Trust Fund.

TABLE 31: TRANSFER OF REMITTANCES FROM THE TREASURY TO MA ORGANIZATIONS

Year	Medicare Advantage Enrollment Increases	Average Annual Per Capita Increases	Ordinary Inflation	Net costs ($ millions)
2017				25.8
2018	7.7%	5.5%	3.2%	28.4
2019	6.7%	5.5%	3.2%	31.0
2020	5.0%	5.5%	3.2%	33.3
2021	3.6%	5.5%	3.2%	35.3
2022	3.8%	5.5%	3.2%	37.5
2023	3.5%	5.5%	3.2%	39.7
2024	3.3%	5.5%	3.2%	41.9
2025	3.1%	5.5%	3.2%	44.2
2026	3.0%	5.5%	3.2%	46.5
2027	2.7%	5.5%	3.2%	48.8
2028	2.5%	5.5%	3.2%	51.1
2029	2.3%	5.5%	2.6%	53.8
2030	2.0%	5.5%	2.6%	56.4
Total 2021-2030				455.2

Deductible Factor for MA Medical Savings Account (MSA) Contracts (§ 422.2440)

CMS is proposing to amend the regulation at § 422.2440 to provide for the application of a deductible factor to the MLR calculation for MA MSA contracts that receive a credibility adjustment. The proposed deductible factor would serve as a multiplier on the credibility factor. CMS is proposing to adopt and codify in new paragraph (g) of § 422.2440 the same deductible factors that appear in the commercial MLR regulations at 45 CFR 158.232(c)(2). For partially credible MA MSA contracts, the deductible factor would range from 1.0 for MA MSA contracts that have a weighted average deductible of less than $2,500 to 1.736 for MA MSA contracts have a weighted average deductible of $10,000 or more.

As discussed in section V.I.4. of this proposed rule, CMS is proposing to add a deductible factor to the MLR calculation for MSAs so that organizations currently offering MSA plans, or those that are considering entering the market, are not deterred from offering MSAs due to concern that they will be unable to meet the MLR requirement as a result of random variations in claims experience. Although we believe that the proposed deductible factors would, if finalized, adequately address any such concerns by making it less likely that an MSA contract will fail to meet the MLR requirement due to random variations in claims experience, we are unable to predict with confidence whether or how the proposed change to the MLR calculation for MA MSA contracts will impact the availability of MA MSAs or the number of beneficiaries enrolled in MA MSAs. Due to this uncertainty, we estimate that the cost impact of the proposed change to the MLR calculation for MA MSAs will be as low as $0 or as high as $43.2 million over 10 years (2021–2030).

We do not anticipate that applying a deductible factor to the MLR calculation for MA MSA contracts, as proposed, would have an impact on remittances to the federal government. For CYs 2014–2017 (the most recent contract year for which MA MSAs have submitted MLR data), no MA MSA contract has failed to meet the 85 percent minimum MLR requirement. If the proposed deductible factors had applied to the MLR calculation for MA MSAs for CYs 2014–2017, although the MLRs for partially credible MA MSAs would have been higher, total remittances by MA MSAs would have remained at $0. We do not anticipate that MSA contracts that currently meet the MLR requirement will have more difficulty doing so if the proposed changes are finalized. We anticipate that new MA MSA contracts that MA organizations may choose to offer as a result of the proposed change will also succeed in meeting the MLR requirement, in light of the experience of current MSAs and in consideration of the more generous credibility adjustment that potential new MSAs would be expected to receive as a result of the application of the proposed deductible factor.

We believe that the cost impact of this proposed change, if any, will be attributable to an increase in MA MSA enrollment as these plans become more widely available as a result of MA organizations choosing to offer MA MSAs in response to the proposed change to the MLR calculation. To develop the upper limit of the cost estimate for this proposal ($43.2 million over 10 years), we assumed that the proposed change to the MLR calculation for MSAs would cause MA MSA enrollment to double over the first 3 years that the proposed change is in effect. We estimated that, relative to enrollment projections under the current regulations, if the proposed changes took effect, MSA enrollment will be 33.33 percent higher in 2021, 66.67 percent higher in 2022, and 100 percent higher in 2023 to 2030. We assumed that half of the new enrollees in MA MSA plans would otherwise have been enrolled in other types of MA plans, and half would otherwise have been enrolled in FFS Medicare.

We then determined the difference between the amount that CMS pays for each MA MSA plan enrollee and the amount CMS pays for each enrollee in a non-MSA MA plan or FFS Medicare. CMS generally incurs greater costs for MA MSA enrollees relative to enrollees in other MA plans because 100 percent of the difference between the MA MSA's projection of the cost of A/B services (referred to as the MSA premium) and the benchmark is deposited in the enrollee's account. By contrast, for MA plans that bid under the benchmark,

CMS retains between 30 percent and 50 percent of the difference between the bid and the benchmark. FFS spending per enrollee is approximately 100 percent of the amount CMS pays to MA plans for each enrollee. Therefore, the cost to the Medicare program for each additional MA MSA enrollee is approximately the same regardless of whether the enrollee would otherwise have been enrolled in a non-MSA MA plan or in FFS Medicare.

The estimated annual cost to the Medicare Trust fund by contract year is presented in Table 32. This estimate takes into account the projected growth in MSA enrollment in the Part C baseline projection supporting the Mid-Session Review of the FY 2020 President's Budget. The estimated annual cost reflects the additional cost to the Medicare program for each beneficiary who enrolls in an MA MSA plan in lieu of a non-MSA MA plan or FFS Medicare, multiplied by the projected increase in the number of enrollees in MA MSA plans.

TABLE 32—ESTIMATED COST PER YEAR TO THE MEDICARE TRUST FUND FOR PROPOSED CHANGES TO MLR CALCULATION FOR MA MSA CONTRACTS

Contract year	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	Contract year 2021–2030
Annual cost (millions)	$1.0	$2.2	$3.6	$4.0	$4.4	$4.8	$5.2	$5.6	$6.0	$6.4	$43.2
Proposed Annual Increase in MA MSA Enrollment	2,478	5,208	8,179	8,531	8,876	9,213	9,531	9,833	10,118	10,354	

10. Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101) and Service Category Cost Sharing Limits for Medicare Parts A and B Services and Per Member Per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113)

MOOP and cost sharing limits are an important beneficiary protection and integral to ensuring that MA enrollees who need extensive or expensive health care because of their health status are not targeted or discriminated against. Requiring MOOP and cost sharing limits in MA plan design is necessary in order not to discourage enrollment by individuals who utilize higher than average levels of health care services (that is, in order for a plan not to be discriminatory in violation of section 1852(b)(1) of the Act). CMS expects adopting transparent rules to govern MOOP and cost sharing limits for local and regional plans, including rules for incorporating out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD, will provide stability for MA organizations and plan enrollees. We expect that our proposed approach to including ESRD costs would increase all in-network and combined MOOP limits for local and regional MA plan types; however, based on our program experience, we believe this is an important and necessary step to ensure that plan designs are not discriminatory and beneficiaries are protected from high and unreasonable financial costs regardless of which MA plan they enroll in. We have coordinated the MOOP and cost sharing proposals in sections VI.A. and VI.B. of this proposed rule in an effort to prevent substantial increases in MOOP limits, cost sharing limits, and premiums to protect beneficiaries, while also proposing reasonable updates and flexibilities for MA organizations to offer sustainable MA plans with stable benefit designs.

CMS expects the proposals in sections VI.A. and VI.B. of this proposed rule, related to transitioning ESRD costs into the data used to set MOOP and cost sharing limits, may result in a combination of savings and costs for MA organizations. Depending upon an individual's health status and health care coverage selections some enrollees may experience increased costs while others may experience decreased costs. CMS is not able to quantify these potential impacts accurately. CMS has not historically estimated potential cost impacts due to changes in cost sharing standards, MOOP limits, and other benefits such as additional telehealth benefits becoming a basic benefit.[110] Accordingly, we provide background and a qualitative discussion to share our rationale. The cost to the MA organization of having a MOOP limit and cost sharing are captured as a supplemental benefit in the bid pricing tool. With a higher MOOP limit or cost sharing, the cost of the MOOP limit and benefits are lower to the MA organization which allows additional rebate dollars to be spent elsewhere (for example, for cost sharing reductions or additional benefits). From an actuarial perspective, on average, the MA enrollee is receiving the same level of benefits in total (of course, individual impacts will vary). As a result, we believe the MOOP and Cost Sharing provisions will have minimal impact.

Before the amendments made by the Cures Act are effective, individuals medically determined to have ESRD cannot enroll in a MA plan, subject to limited exceptions. Generally, those exceptions include the following circumstances: An individual that develops ESRD while enrolled in a MA plan can remain in that plan, or, can enroll in a MA plan in the same organization; if enrolled in a health plan within an organization, an ESRD individual can enroll in a MA plan within that same organization; an ESRD individual enrolled in a plan which is terminated or discontinued has a one-time opportunity to join another plan; or, an individual may enroll in a special needs plan that has obtained a waiver to be open for enrollment to individuals with ESRD. Further information on enrollment exceptions for ESRD individuals is located in Chapter 2 of the Medicare Managed Care Manual. CMS establishes separate rates of payment to address the higher costs MA plans may experience when managing care for these enrollees with ESRD, and will continue to do so after Medicare beneficiaries with diagnoses of ESRD are allowed to enroll in MA plans in greater numbers than they can under the current limitations. For additional information on enrollment impacts from the Cures Act, CMS directs readers to sections IV.A., IX.B.8., and X.C.4. of this proposed rule.

MA organizations have been aware of the program change to allow Medicare beneficiaries with diagnoses of ESRD to enroll in MA since the Cures Act was enacted in December 2016. Following the Cures Act, the OACT has included projections of the number of individuals with diagnoses of ESRD that may enroll in MA within the President's Budget.[111] The OACT will update these projections for the FY 2021 President's Budget. As such, CMS expects MA organizations

[110] April 2019 Final Rule; Past draft and final Call Letters may be accessed at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.*

[111] The Fiscal Year President's Budgets may be accessed at *https://www.govinfo.gov/app/collection/BUDGET/.*

have planned and prepared for this upcoming program change as they have conducted business activities, such as defining plan benefits, provider contracting with network providers, developing case management programs, and making reinsurance arrangements.

CMS recognizes MA organizations are in a competitive market and design their plan bids to manage risk, encourage enrollment, and satisfy Medicare coverage requirements. CMS does not require MA organizations to report these unique approaches and as such cannot quantitatively report an accurate projection of what savings or costs MA organizations may incur from the changes in MOOP and cost sharing limits that will result from implementation of this proposal. CMS's goal in this proposed rule is to provide predictable and transparent MOOP limits and cost sharing standards and to set limits at a level that should not result in significant new costs for MA organizations or enrollees. By taking the program changes from the Cures Act into account within our existing process to set and update MOOP limits and cost sharing standards, we are looking to protect MA enrollees against high out of pocket costs and sudden changes in those costs.

CMS recognizes the MOOP limit in the MA program provides a unique protection to MA enrollees from high out-of-pocket costs. CMS notes beneficiaries with diagnoses of ESRD previously enrolled in Medicare FFS with or without Medigap coverage may experience different cost sharing and out-of-pocket costs if they switch to a MA plan. For example, a Medicare beneficiary with a diagnosis of ESRD enrolled in Medicare FFS (without Medigap or employer coverage) may experience higher out-of-pocket costs annually if their annual health care treatment out-of-pocket costs go above a MOOP limit available in MA. In addition, current and new MA enrollees without diagnoses of ESRD may also experience, or have already experienced, plan changes as MA organizations prepare for increased MA enrollment by beneficiaries with diagnoses of ESRD beyond those already enrolled in the program.

CMS cannot accurately project the cost impacts of these MOOP limit and cost sharing proposals for beneficiaries and MA organizations because potential savings and costs are largely influenced by: (1) The rate of transition for Medicare beneficiaries with diagnoses of ESRD into the MA program, (2) the mechanisms MA organizations choose to address this programmatic change (such as provider contracting, case management, plan benefits designs, and benefit flexibilities including Special Supplemental Benefits for the Chronically Ill, MA uniformity flexibility, as well as MOOP limits and cost sharing flexibilities proposed in this rule). In addition, there are multiple factors that CMS cannot currently disaggregate in order to attribute MOOP limit or cost sharing changes or a portion of cost sharing or MOOP limit changes to the changes in ESRD enrollment policy. These factors include:

- CMS does not collect enrollee level cost sharing information from MA organizations about the individuals reaching the MOOP limit each year;
- The MA enrollee population constantly changes based on individuals who are aging-in to the Medicare program on a monthly basis, existing enrollees dying, and enrollees switching plans;
- MA enrollees who may reach the MOOP limit one year may not meet the MOOP limit the following year; and
- MA organizations prepare plan bids that address many business factors at once, such as capitated payments, quality bonus payments and rebates, provider contracting, reinsurance arrangements, health insurance providers' fee, margins, along with policy changes such as beneficiaries with ESRD diagnoses being able to enroll in the MA program.

By implementing more than two levels of MOOP limits and by providing increased flexibility in setting cost sharing amounts for MA organizations with lower MOOP limits, we expect to encourage plan offerings with more favorable benefit designs for Medicare beneficiaries to choose from. We note that beneficiaries consider the MOOP limit and cost sharing structure when choosing an MA plan, however we do not expect them to face more complex plan options due to these proposals. From a beneficiary perspective, they will see and review the same volume of information about MOOP limits and cost sharing structures as they do currently. We also do not expect these proposals to drive MA plans to offer more plan options than they currently do as they can already create different MOOP limit and cost sharing structures. CMS will continue evaluations and enforcement of the current authority prohibiting plans from misleading beneficiaries in their communication materials and continue efforts to improve plan offerings and plan comparison tools and resources (for example, Medicare & You and 1–800–MEDICARE). In addition, we will disapprove a plan bid if its proposed benefit design substantially discourages enrollment in that plan by certain Medicare-eligible individuals.

11. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)

Our proposal codifies the standards and methodology, with some modifications, used currently to evaluate network adequacy for MA plans and section 1876 cost plans; the proposal includes the list of provider and facility specialty types subject to network adequacy reviews, county type designations and ratios, maximum time and distance standards and minimum number requirements. The proposal also formalizes the CMS exceptions process and requires the annual publishing of the Health Services Delivery (HSD) reference file, which will provide updated numbers and maximums for these standards in subsequent years, and the Provider Supply File, which lists available providers and facilities, including their corresponding office locations and specialty types. CMS will continue to use the current PRA-approved collection of information in conjunction with the HPMS Network Management Module as a means for MA organizations to submit network information when required. As this has been the process for conducting network adequacy reviews since 2016, we do not expect any additional burden on MA plans as it relates to the network adequacy review process.

Our proposal is solely related to the sufficiency of contracted networks that MA organizations must maintain and has no impact on the provision of Medicare benefits that must be provided in either in-network and out-of-network settings. As a result, we do not expect any impact on the Medicare Trust Fund.

However, we propose three modifications to current network adequacy policy that may have qualitative impacts on MA organizations. We propose to reduce the required percentage of beneficiaries residing within maximum time and distance standards in Micro, Rural, and CEAC from 90 percent to 85 percent. We propose to allow for a 10 percentage point credit towards this percentage when MA organizations contract with one or more telehealth providers in the specialties of dermatology, psychiatry, neurology, otolaryngology and cardiology. Similarly, we propose that MA organizations may receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected provider and facility types in states that have CON

laws, or other state imposed anti-competitive restrictions, that limit the number of providers or facilities in a county or state.

With respect to the reduction in percentage of beneficiaries residing within maximum time and distance standards in rural counties, we expect that MA organizations will have a greater likelihood of complying with our reduced percentage in the initial network submission and will not need to request an exception for CMS's consideration. It is not possible to fully quantify the level of effort or hours required for an MA organization to submit an exception request, as they are submitted for multiple reasons. However, generally, we expect that this change will decrease the administrative burden on MA organizations when going through the network review process. Conceivably, the administrative costs included in an MA organization's bid could decrease. However, the decrease in administrative burden could be offset by the increase in administrative burden of contracting with telehealth providers. Additionally, more MA organizations may consider providing contracted services in areas that have traditionally been difficult to establish a sufficient network. The ability to meet compliance standards in new markets is a reasonable factor that may drive MA organization behavior, but we cannot quantify the likelihood of this, as many other factors are considered when entering new markets. In theory, the reduction in the rural percentage could conceivably increase MA enrollment, however our enrollment projections currently do not consider health plans' network adequacy information, and any changes to enrollment projections would be very minor.

By crediting MA organizations 10-percentage points towards the percentage of beneficiaries residing within time and distance standards for contracting with telehealth providers for certain specialties, we anticipate that this will be one of many factors that will help encourage MA organizations to contract with providers that offer telehealth services. However, we do not expect this policy change to significantly alter MA organization contracting patterns related to telehealth providers.

For the 10-percentage point credit for affected providers and facilities in states with CON laws, we expect that MA organizations will have a greater likelihood of complying with network adequacy standards in the initial network submission and will not need to request an exception for CMS's consideration. As we discussed earlier, it is not possible to fully quantify the level of effort or hours required for an MA organization to submit an exception request, but it is possible the administrative costs included in an MA organization's bid could decrease. However, we believe time associated with completing exception requests is nominal will not have a significant impact on the overall administrative costs submitted in a plan's bid.

In summary, we believe this proposal will have a non-quantifiable, negligible economic impact.

12. Service Delivery Request Processes Under PACE (§§ 460.104 and 460.121)

We estimate that our proposed amendments to these provisions, as discussed in section VII.A. of this proposed rule, would result in savings to PACE organizations. To estimate the savings from our proposed revisions to the service delivery request provisions we rely upon the assumptions described in the next section. These assumptions are based on our experience monitoring PACE organizations' compliance with current service delivery request requirements, and on data collected during those monitoring efforts.

We estimate that under the current regulation, the aggregate total annual cost to all PACE organizations for processing service delivery requests is approximately $37.1 million.

We estimated that cost by using the following assumptions. First, we estimate the wages for each of the 11 Interdisciplinary team (IDT) members in order to better estimate a total cost. The eleven disciplines shown are those disciplines required for the IDT composition under § 460.102(b). The Job codes and wages to be used come from the BLS's website allowing 100 for overhead and fringe benefits. Table 33 allows us to estimate the mean hourly wage of the IDT as a whole.

TABLE 33—WAGES FOR IDT STAFF MEMBERS

Occupation title	Occupation code	Mean hourly wage with fringe benefits and overhead ($/hr)
Primary Care Provider	29–1069	196.04
Registered Nurse	29–1141	72.60
Home Care Coordinator (often a RN)	29–1141	72.60
Physical Therapist	29–1123	85.46
Occupational Therapist	29–1122	82.08
Masters of Social Work	21–1022	56.22
Recreational Therapist	29–1125	48.68
Dietician	29–1031	58.86
Driver	53–3022	32.10
Personal Care Attendant	31–1011	24.36
PACE Center Manager	11–9111	109.36
TOTAL		838.36

Currently, when processing a service delivery request, the IDT must determine the appropriate discipline(s) to conduct a reassessment under § 460.104(d)(2) and is responsible for notifying the participant or designated representative of its decision to approve or deny a request under § 460.104(d)(2)(iii). Based on our experiences monitoring PACE organizations, we estimate that the IDT takes approximately 1 hour to handle these responsibilities for each service delivery request (1 * $838.36 = $838.36).

Reassessments performed in response to service delivery requests are varied and may be done by multiple disciplines. For purposes of this

estimate, we assume a registered nurse (RN) and Master's-level Social Worker (MSW) conducts reassessments, and that the total hours for reassessments equals 1.5 hours per discipline. Therefore, we estimate that reassessments would cost (1.5 * $72.60 = $108.90) and (1.5 * $56.22 = $84.33). This is summarized in Table 34.

TABLE 34—COST PER SERVICE DELIVERY REQUEST FOR A PACE ORGANIZATION ASSESSMENT

Professional	Occupational code	Hourly wage ($/hr)	Time (hr)	Total cost ($)
Registered Nurse	29–1141	72.60	1.5	108.90
Masters-level of Social Work	21–1022	56.22	1.5	84.33
Total Cost				193.23

Additionally, once a decision has been rendered, one discipline (usually the MSW) notifies the participant and/or designated representative which we believe takes about 1 hour (1 * $56.22 = $56.22). This is summarized in Table 35.

TABLE 35—COST PER SERVICE DELIVERY REQUEST FOR A PACE ORGANIZATION NOTIFICATION

Professional	Occupational code	Hourly wage ($/hr)	Time (hr)	Total Cost ($)
Masters-level of Social Work	21–1022	56.22	1	56.22

Therefore, the processing of a service delivery request under current regulations is approximately $1,087.81 (838.36 + 108.90 + 84.33 + 56.22) per request.

Additionally, based on combined audit data collected from all PACE organizations in 2017 and 2018, we estimate there are 852.8 service delivery requests per 1000 enrollees (34,146 total service delivery requests for 2017 and 2018 divided by 40,040 the average enrollment for that time period). Consequently, the total cost of processing service delivery requests for 2017–2018 under the current regulations was approximately $37.1 million (852.8 service delivery requests/1000 enrollees * 40,040 thousand enrollees * $1,087.81 per hour of work by the IDT) per year.

We anticipate our proposed regulation would reduce burden on PACE organizations in the following ways. First, the proposal would establish a streamlined approval process for service delivery requests that an IDT member can approve in full at the time the request is made under new § 460.121(e)(2). These approved requests would not need to be brought to the full IDT for review and would not require the IDT to conduct a separate assessment. We also do not anticipate notification of the approval adding an additional burden because the IDT member would approve the request immediately and therefore satisfy the notification requirement at the time the request is made. As discussed in section IX.B.13. of this proposed rule, we estimate:

(i) 20 percent of all service delivery requests are denied, while 80 percent are approved

(ii) Of the 80 percent of service delivery requests that are approved, 50 percent of those are routine (that is, can be approved in full by an IDT member), while 50 percent are not routine.

Consequently,

(a) 341 service delivery requests/1000 enrollees are routine and approved (50 percent routine * 80 percent approved * 852.8 service delivery requests/1000 total)

(b) 171 service delivery requests/1000 enrollees are denied (20 percent * 852.8 service delivery requests/1000 enrollees)

(c) 341 service delivery requests/1000 enrollees are approved but not routine (80 percent approved * 50 percent not routine * 852.8 service delivery requests/1000)

These estimates are summarized in Table 36.

TABLE 36: BREAKOUT OF SERVICE DELIVERY REQUESTS BY TYPE

Line ID	Formula	Item	Number or percentage
(1)		Average enrollment PACE, 2017,2018	40,040
(2)		Total service delivery requests 2017/2018	34,146
(3)	(2 / [(1)/1000]	Service delivery requests per 1000 enrollees	852.8
(4)		Percentage of approved service delivery requests	80%
(5)	100%-80%	Percentage of denied service delivery requests	20%
(6)		Percentage of approved service delivery requests, routine	50%
(7)	(3) * (4)	Total approved service delivery requests	682
(8)	(3) * (5)	Total denied service delivery requests	171
(9)	(7) * (6)	Total easily approved (routine) service delivery requests	341
(10)	(7)-(9)	Total not-easily approved (not routine) service delivery requests	341
(11)	(8)+(9)+(10)	Aggregate service delivery requests per year	853

We are proposing that:

(i) Service delivery requests that can be approved in full at the time the request is made would not require full IDT review, assessment, or a separate notification; Although work is involved in this approval, we are estimating the cost as $0 since (i) no separate assessment is needed, (ii) no separate notification is needed, (iii) the full IDT is not needed and (iv) the estimated time for an IDT member to approve in full an easily approved service delivery request is small and hence the total cost is negligible and can be done as a part of the PACE organization's routine day to day activities.

(ii) Denied service delivery requests require (as is the case under current provisions) IDT review, an in-person assessment and notification.

(iii) Service delivery requests that are approved, but cannot be approved in full at the time the request is made would require IDT review and notification but no assessment.

In section IX.B. of this proposed rule, we indicated five proposals anticipated to create increased burden for PACE organizations: The proposals, their projected first year costs, and their projected annual costs after the first year are summarized in Table 37.

TABLE 37: PAPERWORK COSTS ASSOCIATED WITH THIS PROPOSED RULE

Item	1st Year Cost	Annual Cost All Years	Only 1st Year Cost
Medical record documentation Training (§ 460.210(b))	91,333	-	91,333
Medical record documentation (§ 460.210(b))	559,110	559,110	
Develop written material for tracking services (§ 460.98)	333,395		
Tracking services (§ 460.98)	333,395	333,395	
Extension notification (§ 460.121)	164,612	164,612	
Update for extension notification (§ 460.121)	18,267	-	18,267
Update for patients' rights (§ 460.112)	18,267	-	18,267
Update Appeal Notices (§ 460.122)	45,667		45,667
Totals (in Millions $)	1.6	1.1	0.5

To estimate the total savings over 10 years we proceed as follows:

- We estimate the total savings without additional paperwork for 2017–2018 by subtracting the projected cost under the proposed provisions from the actual cost under the current provisions. Table 37 presents these calculations, showing a $17.5 million savings, without considering paperwork, for 2017–2018.
- For any year between 2021 and 2030, we divide the projected enrollment for that year by the actual enrollment for 2017/2018. Since costs are per 1000 enrollees, this quotient when multiplied by 17.5 million will give the savings for that year without considering paperwork requests.
- Finally, since, paperwork requests are an additional burden, we subtract paperwork costs from the savings to ascertain the projected savings for that year. In subtracting paperwork costs, we must subtract an annual cost in all years and a special one-time first year cost in 2021. Table 38 presents this 10 year projection.

We illustrate these calculations by deriving the $17.5 million savings estimated based upon the data for 2018, and presented in Table 40. That is, if the proposed provisions of this rule had been adopted in 2018, there would have been a savings of $17.5 million. This can be shown as follows:

- Actual Cost (without paperwork) for 2018: 37.1 million
- Cost (without paperwork) if these provisions were adopted: 19.6 million
- Total savings (Difference of the last two rows) 17.5 million

As we explained previously, in order to arrive at the 37.1 million and the 19.6 million for 2018, we considered the following:

- $37.1 = 40,040 (enrollees) * 852.8 service delivery requests/1000 enrollees * $1087.81 (IDT + assessment + notification)
- $19.6 = $12.2 + $7.4 + $0
  - $12.2 = 40,040 enrollees * 341 service delivery requests/1000 enrollee * ($1087.81 − 193.23)
  - $7.4 = 40,040 enrollees * 171 service delivery requests/1000 enrollee * ($1087.81)
  - $0 = $40,040 enrollees * 341 service delivery requests/1000 enrollee * $0

As can be seen, the savings comes from the fact that whereas current regulations require that all 852.8 service delivery requests/1000 enrollees be processed by the IDT (at a cost of $1087.81), the proposed regulations only require that 512 service delivery requests (171 service delivery requests/1000 enrollees that are denied and 341 service delivery requests/1000 enrollees that are approved but not routine) would go to the full IDT for processing, but another 341 service delivery requests would be approved and routine and therefore would not impose any cost on the PACE organization. Additionally, the 341 approved but not routine requests that would go to the IDT would be a reduced cost of $1087.81 − $193.23 since assessments would not be done for those approvals. We believe our proposal will reduce administrative burden on the PACE organization, and allow IDT members to focus more time on providing participant care.

TABLE 38: ITEMIZED AND TOTAL COST PER YEAR FOR CURRENT OPERATIONS AND PROPOSED

	Current	Proposed	Proposed	Proposed	Proposed
	Aggregate Service Delivery Requests	Total Service Delivery Requests Approved - Routine	Total Service Delivery Requests Approved - Not Routine	Total Service Delivery Requests Denied	Total Cost (Millions $) Proposed
Aggregate service delivery requests per 1000 per year	852.8	341	341	171	
Full IDT review	$838.36		$838.36	$838.36	
Assessment	$193.23			$193.23	
Notification	$56.22		$56.22	$56.22	
Total cost/service delivery requests without Paperwork	$1,087.81		$894.58	$1,087.81	
Average Enrollment 2017/2018	40,040		40,040	40,040	
Total Cost (millions) (2017/18)	$37.1		$12.2	$7.4	$19.6
Total Savings 2018 without paperwork					$17.50

TABLE 39: 10-YEAR AGGREGATE PROJECTED SAVINGS FROM PROPOSED PACE PROVISIONS

Year	Enrollment	Base Year Enrollment	Annual Savings 2018/2017 Without Paperwork	Annual Paperwork Cost	Special 1st Year Paperwork Cost	Adjusted Savings Current Year
(1)	(2)	(3)	(4)	(5)	(6)	(2)/(3)*(4)-((5)+(6))
2021	46,311	40,040	$ 17.5	1.1	0.5	18.7
2022	47,697	40,040	$ 17.5	1.1	0	19.8
2023	49,032	40,040	$ 17.5	1.1	0	20.4
2024	50,322	40,040	$ 17.5	1.1	0	20.9
2025	51,594	40,040	$ 17.5	1.1	0	21.5
2026	52,827	40,040	$ 17.5	1.1	0	22.0
2027	54,001	40,040	$ 17.5	1.1	0	22.5
2028	55,120	40,040	$ 17.5	1.1	0	23.0
2029	56,170	40,040	$ 17.5	1.1	0	23.5
2030	57,159	40,040	$ 17.5	1.1	0	23.9

To clarify Table 39, consider the following:

- As noted previously, the actual non-paper savings for the base year, had this provision been implemented in 2018, would have been $17.5 million for the 40,040 enrollees.
- The OACT projects 46,311 PACE enrollees for 2021.
- Since enrollment is projected to increase by a factor of 1.1566 (46,311/40,040), and we are estimating service delivery requests per 1000 enrollees, we project the non-paper savings for 2021 to be 1.1566 * $17.5 = $20.2 million. In other words the 2018 costs under the current regulation and proposed regulation would involve a product of 2018 enrollment (about 40,040) times the number of service requests per 1000. The 2021 costs use the same formula, however the 40,040 is replaced by 46,311. It follows that multiplying 2018 numbers by 46,311/40,040 gives us the correct 2021 number. Since the difference between current and proposed is savings, it follows that multiplying this difference by the ratio of 46,311/40,040 gives the updated savings.)
- However, these are savings without paperwork costs. Table 38 shows that total annual paperwork costs is $1.1 million and additionally there is a special $0.5 million cost for the first year.
- Therefore, the total savings for 2021 would be approximately $20.2 − (1.1 + 0.5) = $18.7 million.
- The other rows are calculated similarly.

Accordingly, our proposals to streamline the processes for addressing service delivery requests in PACE are projected to save PACE organizations $18.7 million in 2021 with a gradual increase in savings to $23.9 million by 2030. These savings are to industry (PACE organizations) because administrative burden is being reduced. Additionally, each blank cell in Table 37 corresponds to a proposal to eliminate an unnecessary burden.

13. Beneficiaries With Sickle Cell Disease (§ 423.100)

Based on analysis of 2018 data, we found that about 683 beneficiaries (1.3 percent) who met the minimum OMS criteria or who had a history of an opioid-related overdose had sickle cell disease and would be affected by the proposed exemption. Since we estimate that less than 10 percent of these 683 beneficiaries would have been targeted for case management, the resulting savings is $0.0 million (10 percent * 683 enrollees * $542.46 for each case management).

D. Alternatives Considered

1. Beneficiaries With History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)

As the Medicare Part D program is a prescription drug benefit and opioid-related overdoses can be due to both prescription opioids, which may be covered under Part D, and illicit opioids, this raises a question of how CMS should define history of opioid-related overdose. CMS considered two options for defining history of an opioid-related overdose plus two alternatives.

Opioid overdose codes (ICD–10) [112] were identified using Medicare FFS Claims data and Part C Encounter data. When considering overdose, we noted that prescription opioids can also be obtained through illegal or illicit means. The available overdose diagnosis codes describe the type of drug involved in the poisoning but do not specify how the drugs were obtained. There is also an unspecified opioid overdose code. Therefore, assumptions were made to classify an overdose code as prescription or illicit. For example, code 40.4 (other synthetic opioids) was classified as illicit opioid overdose but in some cases fentanyl may have been obtained by prescription. Conversely, code 40.2 (other opioids) may include poisoning due to oxycodone which was classified as prescription opioid overdose but may have been obtained illegally.

Option #1. Include beneficiaries with either prescription or illicit opioid-related overdoses. This option would allow CMS to proactively identify the most potential at-risk beneficiaries with a history of opioid-related overdoses, regardless whether the opioid is prescription or illicit, so that they can be reported to the Part D sponsor and reviewed through a DMP. This option represents the largest program size of all of the options. Based on data between July 2017 and June 2018, CMS estimates that there were about 28,891 beneficiaries with prescription or illicit opioid-related overdoses who would have been identified and reported as potential at-risk beneficiaries through the OMS.

Option #1 (Alternative): The program size for this option decreases by 37 percent to 18,268 if we were to identify only those beneficiaries reported to have at least one opioid prescription drug claim during the 6-month OMS measurement period (approximately 63 percent had opioid Part D claim(s)), which means that they have at least one relatively current opioid prescriber.

Option #2: Identify beneficiaries with only prescription opioid-related overdoses. This approach would utilize a 12-month lookback period to identify beneficiaries with a history of prescription opioid overdoses. Based on data between July 2017 and June 2018, CMS estimates that there were about 21,037 beneficiaries with prescription opioid-related overdoses who would be identified and reported by OMS.

Option #2 (Alternative): Since about 72 percent of beneficiaries had at least one Part D opioid claim in the 6-month OMS measurement period, this option decreases the program size to 15,217 beneficiaries if we were to require beneficiaries reported to have at least one opioid prescription drug claim, which means that they have at least one relatively current opioid prescriber.

As noted, the primary impact will result from needing to case manage the additional beneficiaries identified as meeting the proposed definition. At the proposed hour and skill levels defined, this introduces a projected cost of $542.46 per additional beneficiary undergoing case management. The various economic impacts for the alternatives considered are summarized in Table 40.

TABLE 40—ECONOMIC IMPACT OF ALTERNATIVES CONSIDERED

Alternative (criteria)	Number of enrollees affected	Total cost ($)
Option 1	28,891	15,672,211.86
Option 1 (alternative)	18,268	9,909,659.28
Option 2	21,037	11,411,731.02
Option 2 (alternative)	15,217	8,254,613.82

As noted in the preamble, CMS proposed to define history of opioid-related overdose as defined in Option 1 (Alternative). This option incorporates the risk factor most predictive for another overdose or suicide-related event [113] and is commensurate with the Administration's commitment to vigorously address the opioid epidemic. However, this approach keeps a clear tie between opioid-related overdoses and the Part D program by requiring a recent prescription opioid prescriber, which simultaneously increases the likelihood for successful provider outreach through

[112] World Health Organization. (2015). International statistical classification of diseases and related health problems, 10th revision, Fifth edition, 2016. World Health Organization.

[113] Bohnert KM, Ilgen MA, Louzon S, McCarthy JF, Katz IR. Substance use disorders and the risk of suicide mortality among men and women in the US Veterans Health Administration. Addiction. 2017 Jul;112(7):1193–1201. doi: 10.1111/add.13774. Epub 2017 Mar 16. PubMed PMID: 28301070.

case management by the sponsor. We note that should an option be finalized that does not include a requirement for a recent PDE, related changes to other provisions of the DMP regulations may need to be considered. For example, the current regulation language on case management could be revised to include outreach to relevant providers generally, not just prescribers of FADs as there may not be an active current prescriber for purposes of sponsor-led case management.

2. Eligibility for Medication Therapy Management (MTMPs) (§ 423.153)

We initially contemplated requiring that each plan as part of the MTM service develop educational materials regarding the safe disposal of prescription drugs that are controlled substances for its beneficiaries. Though each plan would have had a greater cost to develop such materials, the information might have included more local resources specific to individual plans. However, for the sake of consistency and to reduce burden on MTM programs we are proposing that Part D plans would be required to furnish materials in their MTM programs that meet criteria specified in § 422.111(j) as part of a CMR, TMR, or other follow-up. We also considered whether we should extend MTM eligibility to potential at-risk beneficiaries (PARBs) instead of to just those determined to be at risk. We believe that providing MTM to PARBs might have been beneficial for this population. However, the SUPPORT Act is clear that the extended MTM should apply only to at risk beneficiaries.

3. Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)

The provision regarding educating MA and Part D beneficiaries on opioid risks and alternative treatments has been fully discussed in section III.D. of this proposed rule, including various suggested enrollee groups to receive the information. The impact of this provision was estimated in section IX.B.6. of this proposed rule, which includes discussion of paper versus electronic delivery options.

We emphasize that the SUPPORT Act does not require CMS to set a standard as to which enrollees receive the required information. As indicated in section III.D. of this proposed rule, the SUPPORT Act gives plans flexibility to choose which enrollees to send the information. To facilitate plan choice, we have provided a wide range of alternatives in Table 17 in section IX.B.6. of this proposed rule, including an alternative of sending notices to all Part D enrollees. As can be seen, costs vary between $0.1 and $0.5 million. We refer the reader to the narrative in that section.

4. Permitting a Second, ''Preferred'', Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

In proposing to allow Part D sponsors to have two specialty tiers, under the existing policy at § 423.578(c)(3)(ii), Part D sponsors would be required to permit tiering exceptions between the two specialty tiers. CMS is also considering permitting Part D sponsors to exempt tiering exceptions between the two specialty tiers, but CMS is concerned that removing the Part D enrollee protection requiring exceptions between the two specialty tiers could negate benefits that might otherwise have accrued to Part D enrollees under a two specialty tier policy when there is a therapeutic alternative on the preferred specialty tier that a Part D enrollee is unable to take.

Additionally, although CMS is proposing to codify at § 423.104(d)(2)(iv)(E) the maximum allowable cost sharing under current policy, because CMS notes that the deductible applies to all tiers and it is unclear that we should continue to differentiate the specialty tier from other tiers on the basis of the deductible, CMS is also considering decreasing the maximum permissible cost sharing to the 25 percent Defined Standard coinsurance for Part D plans with decreased or no deductibles. As a result, we would anticipate that Part D sponsors would need to raise cost sharing on non-specialty drugs to maintain actuarial equivalence. If this applies to all plans, then there should be no budget impact, as they must still return to a basic benefit design that is actuarially equivalent to the Defined Standard benefit, and there will be no adverse selection. Additionally, we do not expect impacts from this proposal to the private sector, as additional specialty tiers already exist in that market. Plans with a high proportion of dual-eligible enrollees are less likely to offer a second specialty tier, because the lower cost sharing would be less impactful for those beneficiaries. As a result, we don't expect material impacts to Medicaid costs.

Finally, although CMS is proposing at § 423.104(d)(2)(iv)(B) to increase the specialty-tier cost threshold for all plan years in which CMS determines that no less than a ten percent increase in the specialty-tier cost threshold, before rounding ''to'' the nearest $10 increment, in order to reestablish the one percent outlier threshold, CMS is also considering a change in this methodology such that CMS would always round ''up'' to the nearest $10 increment. This rounding up methodology would: (a) Ensure that the new specialty-tier cost threshold actually meets the one percent outlier threshold, and (b) provide more stability to the specialty-tier cost threshold. Although the $780 30-day equivalent ingredient cost we determined to be the specialty-tier cost threshold for this proposed rule did not require rounding, had we arrived at a 30-day equivalent ingredient cost of, for example, $772, rounding up to $780 30-day equivalent ingredient cost would have an insignificant impact on the number of drugs meeting the specialty-tier cost threshold.

5. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

We propose to require that each Part D plan adopt a beneficiary RTBT by January 1, 2022. We had considered requiring that this regulatory action occur by January 1, 2021 to coincide with the requirement of a prescriber RTBT and the other regulatory actions in this rule. However, we wanted to ensure that plans had adequate time to focus on implementing the prescriber RTBT by the currently mandated January 1, 2021 deadline.

We also considered requiring that plans display this information via a third party website or web application. However, since we discovered that plans already have patient portals that provide some of the mandated information, we believe it would be less confusing for beneficiaries to keep this information on the plan portal. In addition, it would be less of a burden on plans for them put the information on the portals, rather than supply the information to a third party.

E. Accounting Statement and Table

The following table summarizes savings, costs, and transfers by provision. As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Table 41, we have prepared an accounting statement showing the savings, costs, and transfers associated with the provisions of this proposed rule for calendar years 2021 through 2030. Table 41 is based on Tables 42A, 42B, and 42C which lists savings, costs, and transfers by provision. Table 41 is expressed in millions of dollars with both costs and savings listed as positive numbers. The sign of the transfers follow the convention of Table 41 with positive

numbers reflecting costs (as transfers) to government entities (the Medicare Trust Fund and the Treasury) and negative numbers reflecting savings to government entities. As can be seen, the net annualized savings of this rule is about $6 million per year. The raw savings over 10 years is $292 million. Due to transfers, there is net annualized reduced spending by government agencies (the Medicare Trust Fund and Treasury) of $370–$405 million. A breakdown of these savings from various perspectives may be found in Table 41.

TABLE 41—ACCOUNTING TABLE

[Millions $]*

Item	Annualized at 7%	Annualized at 3%	Period	Who is impacted
Net Annualized Monetized Savings.	5.8	6.3	Contract Years 2021–2030.	Federal government, MA organizations and Part D Sponsors.
Annualized Monetized Savings.	28.8	29.0	Contract Years 2021–2030.	Federal government, MA organizations and Part D Sponsors.
Annualized Monetized Cost.	23.0	22.7	Contract Years 2021–2030.	Federal government, MA organizations and Part D Sponsors.
Transfers	(369.0)	(406.5)	Contract Years 2021–2030.	Transfers between the Dept of Treasury and CMS (Medicare Trust Fund, Plans, and Sponsors).

* The ESRD enrollment and Kidney acquisition cost provisions which affected the pre-statutory baseline but did not further impact the codifications of this rule would have added $128.3 and $113.1 million respectively in annualized transfer savings, resulting in total annualized transfer savings of $497.3 and $519.7 savings at 7 percent and 3 percent respectively.

The following Table 42 summarizes savings, costs, and transfers by provision and forms a basis for the accounting table. For reasons of space, Table 42 is broken into Table 42A (2021 through 2024), Table 42B (2025 through 2028), and Table 42C (2029–2030), as well as raw totals. In these tables, all numbers are positive; positive numbers in the savings columns indicate actual dollars saved while positive numbers in the costs columns indicate actual dollars spent; the aggregate row indicates savings less costs and does not include transfers. All numbers are in millions. Tables 42A, B, and C form the basis for Table 41 and for the calculation to the infinite horizon discounted to 2016 and mentioned in the conclusion.

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TABLE 42A: AGGREGATE SAVINGS, COST, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2021 THROUGH 2024

	2021 Savings	2021 Cost	2021 Transfers	2022 Savings	2022 Cost	2022 Transfers	2023 Savings	2023 cost	2023 Transfers	2024 Savings	2024 Cost	2024 Transfers
Total Savings	24.5			27.5			28.1			28.7		
Total Costs		34.0			21.3			21.3			21.3	
Aggregate Total	(9.5)			6.2			6.8			7.4		
Total Transfers			36.3			39.7			43.3			(322.2)
Health Plan Quality Rating System												(368.1)
MTMP		0.7			0.7			0.7			0.7	
SNP MOCs		0.3			0.3			0.3			0.3	
MLR Regulation			35.3			37.5			39.7			41.9
MSA MLR			1.0			2.2			3.6			4.0
PACE Service Delivery Requests	18.7			19.8			20.4			20.9		

	2021 Savings	2021 Cost	2021 Transfers	2022 Savings	2022 Cost	2022 Transfers	2023 Savings	2023 cost	2023 Transfers	2024 Savings	2024 Cost	2024 Transfers
Fraud & Abuse Pt C, D		15.0			9.5			9.5			9.5	
Educating At-Risk Enrollees		0.1										
RTBT		4.6			0.4			0.4			0.4	
Pharmacy Performance Measures		0.2			0.2			0.2			0.2	
Mandatory DMP					0.1			0.1			0.1	
DMP Paperwork		3.1			0.1			0.1			0.1	
DMP Case Management		9.9			10.0			10.0			10.0	
DMP Drug Savings	5.8			7.7			7.7			7.7		

TABLE 42B: AGGREGATE SAVINGS, COST, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2025 THROUGH 2028

	2025 Savings	2025 Cost	2025 Transfers	2026 Savings	2026 Cost	2026 Transfers	2027 Savings	2027 Cost	2027 Transfers	2028 Savings	2028 Cost	2028 Transfers
Total Savings	29.2			29.8			30.3			30.8		
Total Costs		21.3			21.3			21.3			21.3	
Aggregate Total	7.9			8.5			9.0			9.5		
Total Transfers			(489.3)			(555.4)			(561.3)			(717.0)
Health Plan Quality Rating System			(537.9)			(606.7)			(615.3)	-		(773.7)
MTMP		0.7			0.7			0.7			0.7	
SNP MOCs		0.3			0.3			0.3			0.3	
MLR Regulation			44.2			46.5			48.8			51.1
MSA MLR			4.4			4.8			5.2			5.6
PACE Service Delivery Requests	21.5			22.0			22.5			23.0		

	2025 Savings	2025 Cost	2025 Transfers	2026 Savings	2026 Cost	2026 Transfers	2027 Savings	2027 Cost	2027 Transfers	2028 Savings	2028 Cost	2028 Transfers
Fraud & Abuse Pt C, D		9.5			9.5			9.5			9.5	
Educating At-Risk Enrollees												
RTBT		0.4			0.4			0.4			0.4	
Pharmacy Performance Measures		0.2			0.2			0.2			0.2	
Mandatory DMP		0.1			0.1			0.1			0.1	
DMP Paperwork		0.1			0.1			0.1			0.1	
DMP Case Management		10.0			10.0			10.0			10.0	
DMP Drug Savings	7.7			7.7			7.7			7.7		

TABLE 42C: AGGREGATE SAVINGS, COST, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2029 THROUGH 2030 AND RAW TOTALS

	2029 Savings	2029 Cost	2029 Transfers	2030 Savings	2030 Costs	2030 Transfers	Raw 10 Year Totals (Savings)	Raw 10 Year Totals (Costs)	Raw 10 year totals (Transfers)
Total Savings	31.22			31.7			291.7		
Total Costs		21.3			21.3			225.5	
Aggregate Total	9.9			10.4			66.2		(4,359.4)
Total Transfers			(897.0)			(936.6)			
Health Plan Quality Rating System			(956.8)			(999.4)			(4,857.8)
MTMP		0.7			0.7			7.0	
SNP MOCs		0.3			0.3			3.4	
MLR Regulation			53.8			56.4			455.2
MSA MLR			6.0			6.4			43.2
PACE Service Delivery Requests	23.5			23.9			216.3		

	2029 Savings	2029 Cost	2029 Transfers	2030 Savings	2030 Costs	2030 Transfers	Raw 10 Year Totals (Savings)	Raw 10 Year Totals (Costs)	Raw 10 year totals (Transfers)
Fraud & Abuse Pt C, D		9.5			9.5			100.1	
Educating At-Rrisk Enrollees								0.1	
RTBT		0.4			0.4			8.0	
Pharmacy Performance Measures		0.2			0.2			2.4	
Mandatory DMP		0.1			0.1			0.8	
DMP Paperwork		0.1			0.1			3.9	
DMP Case Management		10.0			10.0			99.9	
DMP Drug Savings	7.7			7.7			75.4		

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The following information supplements Table 42 and also identifies how impacts calculated in section IX of this proposed rule affect the calculations of this section and the tables.

- For two provisions, DMP and PACE, this Regulatory Impact Analysis provides tables summarizing a variety of impacts with line items for the paperwork burdens of section IX of this proposed rule. Thus the section IX impacts are reflected both in Table 42 (summary table) and 40 (monetized table) as well as in special tables in this section.
- For five provisions, MTMP, RTBT, SNP MOCs, pharmacy, and Fraud and Abuse, the only impacts are calculated in section IX of this proposed rule. These five provisions have those section IX impacts listed in Table 42.
- For outreach to at risk beneficiaries, which was estimated in section IX of this proposed rule, only the system updates and preparation of outreach are listed in Table 42. Although Table 19 of section IX of this proposed rule does list additional impacts, the mailing of material to beneficiaries, since CMS was not given the authority to decide on the

cohort of beneficiaries to whom to send this information, we have omitted mailing costs from Table 42 and instead solicited stakeholder feedback.

• For two provisions, Parts C and D SEPs, and ESRD enrollment, calculations of impact, either paperwork or on the Medicare Trust Fund have been provided in the narrative along with tables providing 10-year summaries. However, since these impacts are already reflected in current spending, in other words, since the provisions do not change current spending, these impacts have not been included in Table 42.

• There is a cost of $0.7 million arising from burden to beneficiaries for filling out enrollment forms as a result of allowing ESRD beneficiaries to join plans and expected increased in MSA enrollment. These costs have been duly noted in section IX of this proposed rule but were not included in Table 42 since it deals mainly with impacts on the Medicare Trust Fund and industry.

• For two provisions, D–SNP look alike and MSA MLR, the impact calculated in section IX of this proposed rule is $0.0 million and hence these amounts are not included in Table 42. They are however included in Table 10 of section IX of this proposed rule.

F. Conclusion

As indicated in Table 41, we estimate that this proposed rule generates annualized cost savings of approximately $5.8 to 6.3 million per year over 2021 through 2030. As indicated in Table 42, the primary driver of savings are (i) proposed revisions to the PACE program resulting in greater efficiencies and (ii) increased vigilance for at-risk beneficiaries with a consequent reduction in drug costs. These savings are offset by costs from Fraud and Abuse efforts and a variety of outreach efforts to at-risk beneficiaries.

As indicated in Table 42, the government agencies have a net reduction in spending of $4.4 billion over 10 years. The primary driver of reduction is the use of the Tukey outlier deletion for Star Ratings. This reduction in Medicare Trust Fund spending is offset by several items increasing spending such as the MLR provisions which reduce civil penalties to the Treasury, and the MSA provisions which may result in increased enrollment in MSA plans and consequent increased spending by the Trust Fund,

G. Reducing Regulation and Controlling Regulatory Costs

This proposed rule, if finalized, is tentatively expected to be a deregulatory action under Executive Order 13771. The Department preliminarily estimates that this rule generates $4.4 million in annualized savings at a 7 percent discount rate, discounted relative to 2016, over a perpetual time horizon.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays.

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 455

Fraud, Grant programs—health, Health facilities, Health professions, Investigations, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to reads as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.370(a) is amended by—

■ a. Revising paragraph (1) of the definition of ''Credible allegation of fraud''; and

■ b. Adding the definition for ''Fraud hotline tip'' in alphabetical order.

The revision and addition read as follows:

§ 405.370 Definitions.

(a) * * *

Credible allegation of fraud. * * *

(1) Fraud hotline tips verified by further evidence.

* * * * *

Fraud hotline tip. A complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 3. The authority citation for part 417 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, 42 U.S.C. 300e, 300e–5, and 300e–9, and 31 U.S.C. 9701.

■ 4. Section 417.416 is amended by adding paragraph (e)(3) to read as follows:

§ 417.416 Qualifying condition: Furnishing of services.

* * * * *

(e) * * *

(3) The HMO or CMP must meet network adequacy standards specified in § 422.116 of this chapter.

■ 5. Section 417.496 is added to read as follows:

§ 417.496 Cost plan crosswalk.

(a) *General rules*—(1) *Definition.* Crosswalk means the movement of enrollees from one plan (or plan benefit package (PBP)) to another plan (or PBP) under a cost plan contract between the CMP or HMO and CMS. To crosswalk enrollees from one PBP to another is to change the enrollment from the first PBP to the second.

(2) *Prohibition.* (i) Crosswalks are prohibited between different contracts.

(ii) Crosswalks are prohibited between different plan IDs unless the crosswalk to a different plan ID meets the requirements in paragraph (c)(1)(i) of this section.

(3) *Compliance with renewal/nonrenewal rules.* The cost plan must comply with renewal and nonrenewal rules in §§ 417.490 and 417.492 in order to complete plan crosswalks.

(b) *Allowable crosswalk types.* All cost plans may perform a crosswalk in the following circumstances:

(1) *Renewal.* A plan in the following contract year that links to a current contract year plan and retains the entire service area from the current contract year. The following contract year plan must retain the same plan ID as the current contract year plan.

(2) *Consolidated renewal.* A plan in the following contract year that combines 2 or more PBPs. The plan ID for the following contract year must retain one of the current contract year plan IDs.

(3) *Renewal with a service area expansion (SAE).* A plan in the following contract year plan that links to a current contract year plan and retains all of its plan service area from the current contract year, but also adds one or more new counties. The following year contract plan must retain the same plan ID as the current contract year plan.

(4) *Renewal with a service area reduction (SAR).* A plan in the following contract year that links to a current contract year plan and only retains a portion of its plan service area. The following contract year plan must retain the same plan ID as the current contract year plan. The crosswalk is limited to the enrollees in the remaining service area.

(c) *Exception.* (1) In order to perform a crosswalk that is not specified in paragraph (b) of this section, a cost organization must request an exception. CMS reviews requests and permits a crosswalk exception in the following circumstance:

(i) Except as specified in paragraph (c)(1)(ii) of this section, terminating cost plans offering optional benefits may transfer enrollees from one of the PBPs under its contract to another PBP under its contract, including new PBPs that have no optional benefits or optional benefits different than those in the terminating PBP.

(ii) A terminating cost plan cannot move an enrollee from a PBP that does not include Part D to a PBP that does include Part D.

(iii) If the terminated supplemental benefit includes Part D and the new PBP does not, enrollees must receive written notification about the following:

(A) That they are losing Part D coverage;

(B) The options for obtaining Part D; and

(C) The implications of not getting Part D through some other means.

(2) [Reserved]

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 6. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 7. Section 422.2 is amended by revising the definition of ''Institutionalized'' and adding the definition of ''Parent organization'' in alphabetical order to read as follows:

§ 422.2 Definitions.

* * * * *

Institutionalized means, for the purposes of defining a special needs individual and for the open enrollment period for institutionalized individuals at § 422.62(a)(4), an MA eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in one of the following long-term care facility settings:

(1) Skilled nursing facility (SNF) as defined in section 1819 of the Act (Medicare).

(2) Nursing facility (NF) as defined in section 1919 of the Act (Medicaid).

(3) Intermediate care facility for individuals with intellectual and developmental disabilities as defined in section 1905(d) of the Act.

(4) Psychiatric hospital or unit as defined in section 1861(f) of the Act.

(5) Rehabilitation hospital or unit as defined in section 1886(d)(1)(B) of the Act.

(6) Long-term care hospital as defined in section 1886(d)(1)(B) of the Act.

(7) Hospital which has an agreement under section 1883 of the Act (a swing-bed hospital).

(8) Subject to CMS approval, a facility that is not listed in paragraphs (1) through (7) of this definition but meets both of the following:

(i) Furnishes similar long-term, healthcare services that are covered under Medicare Part A, Medicare Part B, or Medicaid; and

(ii) Whose residents have similar needs and healthcare status as residents of one or more facilities listed in paragraphs (1) through (7) of this definition.

* * * * *

Parent organization means the legal entity that exercises a controlling interest, through the ownership of shares, the power to appoint voting board members, or other means, in a Part D sponsor or MA organization, directly or through a subsidiary or subsidiaries, and which is not itself a subsidiary of any other legal entity.

* * * * *

■ 8. Section 422.3 is added to read as follows:

§ 422.3 MA organizations' use of reinsurance.

(a) An MA organization may obtain insurance or make other arrangements for the cost of providing basic benefits to an individual enrollee that either:

(1) The aggregate value of which exceeds an aggregate level that is greater than or equal to $10,000 during a contract year; or

(2) If the MA organization uses insurance or makes arrangements for sharing such costs proportionately on a first dollar basis, the value of the insured risk does not exceed a value which is actuarially equivalent to the costs described in paragraph (a)(1) of this section.

(b) [Reserved]

§ 422.50 [Amended]

■ 9. Section 422.50 is amended in paragraph (a)(2) introductory text by removing the phrase ''Has not been'' and adding in its place the phrase ''For coverage before January 1, 2021, has not been''.

§ 422.52 [Amended]

■ 10. Section 422.52 is amended in paragraph (c) by removing the phrase ''CMS may waive § 422.50(a)(2)'' and adding in its place the phrase ''For plan years beginning before January 1, 2021, CMS may waive § 422.50(a)(2)''.

■ 11. Section 422.62 is amended by—

■ a. Revising paragraphs (b) introductory text and (b)(3) introductory text;

■ b. Redesignating paragraph (b)(4) as paragraph (b)(26); and

■ c. Adding a new paragraph (b)(4) and paragraphs (b)(5) through (25).

The revisions and additions read as follows:

§ 422.62 Election of coverage under an MA plan.

* * * * *

(b) *Special election periods (SEPs).* An individual may at any time (that is, not limited to the annual coordinated election period) discontinue the election of an MA plan offered by an MA organization and change his or her election from an MA plan to original Medicare or to a different MA plan under any of the following circumstances:

* * * * *

(3) The individual demonstrates to CMS that—

* * * * *

(4) The individual is making an MA enrollment request into or out of an employer sponsored MA plan, is disenrolling from an MA plan to take employer sponsored coverage of any kind, or is disenrolling from employer sponsored coverage (including COBRA coverage) to elect an MA plan. This SEP is available to individuals who have (or are enrolling in) an employer or union

sponsored MA plan and ends 2 months after the month the employer or union coverage of any type ends. The individual may choose an effective date that is not earlier than the first of the month following the month in which the election is made and no later than up to 3 months after the month in which the election is made.

(5) The individual is enrolled in an MA plan offered by an MA organization that has been sanctioned by CMS and elects to disenroll from that plan in connection with the matter(s) that gave rise to that sanction.

(i) Consistent with disclosure requirements at § 422.111(g), CMS may require the MA organization to notify current enrollees that if the enrollees believe they are affected by the matter(s) that gave rise to the sanction, the enrollees are eligible for a SEP to elect another MA plan or disenroll to original Medicare and enroll in a PDP.

(ii) The SEP starts with the imposition of the sanction and ends when the sanction ends or when the individual makes an election, whichever occurs first.

(6)(i) The individual is enrolled in a section 1876 cost contract that is not renewing its contract for the area in which the enrollee resides.

(ii) This SEP begins December 8 of the then-current contract year and ends on the last day of February of the following year.

(7) The individual is disenrolling from an MA plan to enroll in a Program of All-inclusive Care for the Elderly (PACE) organization or is enrolling in an MA plan after disenrolling from a PACE organization.

(i) An individual who disenrolls from PACE has a SEP for 2 months after the effective date of PACE disenrollment to elect an MA plan.

(ii) An individual who disenrolls from an MA plan has a SEP for 2 months after the effective date of MA disenrollment to elect a PACE plan.

(8) The individual terminated a Medigap policy upon enrolling for the first time in an MA plan and is still in a ''trial period'' and eligible for ''guaranteed issue'' of a Medigap policy, as outlined in section 1882(s)(3)(B)(v) of the Act.

(i) This SEP allows an eligible individual to make a one-time election to disenroll from his or her first MA plan to join original Medicare at any time of the year.

(ii) This SEP begins upon enrollment in the MA plan and ends after 12 months of enrollment or when the individual disenrolls from the MA plan, whichever is earlier.

(9) Until December 31, 2020, the individual became entitled to Medicare based on ESRD for a retroactive effective date (whether due to an administrative delay or otherwise) and was not provided the opportunity to elect an MA plan during his or her Initial Coverage Election Period (ICEP).

(i) The individual may prospectively elect an MA plan offered by an MA organization, provided—

(A) The individual was enrolled in a health plan offered by the same MA organization the month before their entitlement to Parts A and B;

(B) The individual developed ESRD while a member of that health plan; and

(C) The individual is still enrolled in that health plan.

(ii) This SEP begins the month the individual receives the notice of the Medicare entitlement determination and continues for 2 additional calendar months after the month the notice is received.

(10) The individual became entitled to Medicare for a retroactive effective date (whether due to an administrative delay or otherwise) and was not provided the opportunity to elect an MA plan during their initial coverage election period (ICEP). This SEP begins the month the individual receives the notice of the retroactive Medicare entitlement determination and continues for 2 additional calendar months after the month the notice is received. The effective date would be the first of the month following the month in which the election is made but would not be earlier than the first day of the month in which the notice of the Medicare entitlement determination is received by the individual.

(11)(i) The individual enrolled in an MA special needs plan (SNP) and is no longer eligible for the SNP because he or she no longer meets the applicable special needs status.

(ii) This SEP begins the month the individual's special needs status changes and ends when the individual makes an enrollment request or 3 calendar months after the effective date of involuntary disenrollment from the SNP, whichever is earlier.

(12) The individual belongs to a qualified State Pharmaceutical Assistance Program (SPAP) and is requesting enrollment in an MA–PD plan.

(i) The individual may make one MA election per year.

(ii) This SEP is available while the individual is enrolled in the SPAP and, upon loss of eligibility for SPAP benefits, for an additional 2 calendar months after either the month of the loss of eligibility or notification of the loss, whichever is later.

(13)(i) The individual has severe or disabling chronic conditions and is eligible to enroll into a Chronic Care SNP designed to serve individuals with those conditions. The SEP is for an enrollment election that is consistent with the individual's eligibility for a Chronic Care SNP. Individuals enrolled in a Chronic Care SNP who have a severe or disabling chronic condition which is not a focus of their current SNP are eligible for this SEP to request enrollment in a Chronic Care SNP that focuses on this other condition. Individuals who are found after enrollment not to have the qualifying condition necessary to be eligible for the Chronic Care SNP are eligible for a SEP to enroll in a different MA plan.

(ii) This SEP is available while the individual has the qualifying condition and ends upon enrollment in the Chronic Care SNP. This SEP begins when the MA organization notifies the individual of the lack of eligibility and extends through the end of that month and the following 2 calendar months. The SEP ends when the individual makes an enrollment election or on the last day of the second of the 2 calendar months following notification of the lack of eligibility, whichever occurs first.

(14) The individual is enrolled in an MA–PD plan and requests to disenroll from that plan to enroll in or maintain other creditable prescription drug coverage.

(i) This SEP is available while the individual is enrolled in an MA–PD plan. The effective date of disenrollment from the MA plan is the first day of the month following the month a disenrollment request is received by the MA organization.

(ii) Permissible enrollment changes during this SEP are to disenroll from an MA–PD plan and elect original Medicare or to elect an MA-only plan, resulting in disenrollment from the MA–PD plan.

(15) The individual is requesting enrollment in an MA plan offered by an MA organization with a Star Rating of 5 Stars. An individual may use this SEP only once for the contract year in which the MA plan was assigned a 5-star overall performance rating, beginning the December 8th before that contract year through November 30th of that contract year.

(16) The individual is a non-U.S. citizen who becomes lawfully present in the United States.

(i) This SEP begins the month the individual attains lawful presence status and ends the earlier of when the

individual makes an enrollment election or 2 calendar months after the month the individual attains lawful presence status.

(ii) [Reserved]

(17) The individual was adversely affected by having requested, but not received, required notices or information in an accessible format, as outlined in section 504 of the Rehabilitation Act of 1973 within the same timeframe that the MA organization or CMS provided the same information to individuals who did not request an accessible format.

(i) The SEP begins at the end of the election period during which the individual was seeking to make an enrollment election and the length is at least as long as the time it takes for the information to be provided to the individual in an accessible format.

(ii) MA organizations may determine eligibility for this SEP when the criterion is met, ensuring adequate documentation of the situation, including records indicating the date of the individual's request, the amount of time taken to provide accessible versions of the requested materials and the amount of time it takes for the same information to be provided to an individual who does not request an accessible format.

(18) Individuals affected by a Federal Emergency Management Agency (FEMA)-declared weather-related emergency or major disaster are eligible for a SEP to make an MA enrollment or disenrollment election. The SEP is available from the start of the incident period and for 4 calendar months after the start of the incident period. And individual is eligible for this SEP provided the individual—

(i)(A) Resides, or resided at the start of the incident period, in an area for which FEMA has declared an emergency or a major disaster and has designated affected counties as being eligible to apply for individual or public level assistance; or

(B) Does not reside in the affected areas but relies on help making healthcare decisions from one or more individuals who reside in the affected areas; and

(ii) Was eligible for an election period at the time of incident period; and

(iii) Did not make an election during that election period due to the weather-related emergency or major disaster.

(19) The individual experiences an involuntary loss of creditable prescription drug coverage, including a reduction in the level of coverage so that it is no longer creditable and excluding any loss or reduction of creditable coverage that is due to a failure to pay premiums.

(i) The individual is eligible to request enrollment in an MA–PD plan.

(ii) The SEP begins when the individual is notified of the loss of creditable coverage and ends 2 calendar months after the later of the loss (or reduction) or the individual's receipt of the notice.

(iii) The effective date of this SEP is the first of the month after the enrollment election is made or, at the individual's request, may be up to 3 months prospective.

(20) The individual was not adequately informed of a loss of creditable prescription drug coverage, or that they never had creditable coverage. CMS determines eligibility for this SEP on a case-by-case basis, based on its determination that an entity offering prescription drug coverage failed to provide accurate and timely disclosure of the loss of creditable prescription drug coverage or whether the prescription drug coverage offered is creditable.

(i) The individual is eligible for one enrollment in, or disenrollment from, an MA–PD plan.

(ii) This SEP begins the month of CMS' determination and continues for 2 additional calendar months following the determination.

(21) The individual's enrollment or non-enrollment in an MA–PD plan is erroneous due to an action, inaction, or error by a Federal employee.

(i) The individual is permitted enrollment in, or disenrollment from, the MA–PD plan, as determined by CMS.

(ii) This SEP begins the month of CMS approval of this SEP on the basis that the individual's enrollment was erroneous due to an action, inaction, or error by a Federal employee and continues for 2 additional calendar months following this approval.

(22) The individual is eligible for an additional Part D Initial Election Period, such as an individual currently entitled to Medicare due to a disability and who is attaining age 65.

(i) The individual is eligible to make an MA election to coordinate with the additional Part D Initial Election Period.

(ii) The SEP may be used to disenroll from an MA plan, with or without Part D benefits, to enroll in original Medicare, or to enroll in an MA plan that does not include Part D benefits, regardless of whether the individual uses the Part D Initial Election Period to enroll in a PDP.

(iii) The SEP begins and ends concurrently with the additional Part D Initial Election Period.

(23) Individuals affected by a significant change in plan provider network are eligible for a SEP that permits disenrollment from the MA plan that has changed its network to another MA plan or to original Medicare. This SEP can be used only once per significant change in the provider network.

(i) The SEP begins the month the individual is notified of eligibility for the SEP and extends an additional 2 calendar months thereafter.

(ii) An enrollee is affected by a significant network change when the enrollee is assigned to, currently receiving care from, or has received care within the past 3 months from a provider or facility being terminated from the provider network.

(iii) When instructed by CMS, the MA plan that has significantly changed its network must issue a notice, in the form and manner directed by CMS, that notifies enrollees who are eligible for this SEP of their eligibility for the SEP and how to use the SEP.

(24) The individual is enrolled in a plan offered by an MA organization that has been placed into receivership by a state or territorial regulatory authority. The SEP begins the month the receivership is effective and continues until it is no longer in effect or until the enrollee makes an election, whichever occurs first. When instructed by CMS, the MA plan that has been placed under receivership must notify its enrollees, in the form and manner directed by CMS, of the enrollees' eligibility for this SEP and how to use the SEP.

(25) The individual is enrolled in a plan that has been identified with the low performing icon in accordance with § 422.166(h)(1)(ii). This SEP exists while the individual is enrolled in the low performing MA plan.

* * * * *

■ 12. Section 422.68 is amended by revising paragraph (d) to read as follows:

§ 422.68 Effective dates of coverage and change of coverage.

* * * * *

(d) *Special election periods.* For an election or change of election made during a special election period as described in § 422.62(b), the coverage or change in coverage is effective the first day of the calendar month following the month in which the election is made, unless otherwise noted.

* * * * *

■ 13. Section 422.100 is amended by—

■ a. Revising paragraphs (c)(1) and (2);

■ b. Redesignating paragraph (d)(2) as paragraph (d)(2)(i);

■ c. Adding paragraph (d)(2)(ii); and

■ d. Revising paragraphs (f)(4) through (6), (j), and (m)(5)(iii).

The revisions and addition read as follows:

§ 422.100 General requirements.

* * * * *

(c) * * *

(1) Basic benefits are all items and services (other than hospice care or, beginning in 2021, coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B of Medicare, including additional telehealth benefits offered consistent with the requirements at § 422.135.

(2) Supplemental benefits are benefits offered under § 422.102.

(i) Supplemental benefits consist of—

(A) Mandatory supplemental benefits are services not covered by Medicare that an MA enrollee must purchase as part of an MA plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost sharing.

(B) Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost sharing. These services may be grouped or offered individually.

(ii) Supplemental benefits must meet the following requirements:

(A) Except in the case of special supplemental benefit for the chronically ill (SSBCI) offered in accordance with § 422.102(f) that are not primarily health related, the benefits diagnose, compensate for physical impairments or act to ameliorate the functional or psychological impact of injuries or health conditions, or reduce avoidable emergency and health care utilization;

(B) The MA organization incurs a non-zero direct medical cost, except that in the case of a SSBCI that is not primarily health related that is offered in accordance with § 422.102, the MA organization may instead incur a non-zero direct non-administrative cost; and

(C) The benefits are not covered by Medicare.

(d) * * *

(2) * * *

(ii) MA plans may provide supplemental benefits (such as specific reductions in cost sharing or additional services or items) that are tied to disease state or health status in a manner that ensures that similarly situated individuals are treated uniformly; there must be some nexus between the health status or disease state and the specific benefit package designed for enrollees meeting that health status or disease state.

* * * * *

(f) * * *

(4) Except as provided in paragraph (f)(5) of this section, for each year beginning on or after January 1, 2022, MA local plans (as defined in § 422.2) must establish a maximum out-of-pocket (MOOP) limit for basic benefits that is consistent with this paragraph (f)(4). MA organizations are responsible for tracking out-of-pocket spending incurred by the enrollee, and must alert enrollees and contracted providers when the MOOP limit is reached.

(i) CMS sets up to three MOOP limits using projections of beneficiary spending that are based on the most recent, complete Medicare Fee-for-Service (FFS) data subject to paragraph (f)(4)(vii) of this section.

(ii) An MA organization that establishes a plan's MOOP limit at a dollar amount within the range specified in paragraphs (f)(4)(ii)(A) through (C) of this section is considered to have the corresponding mandatory, intermediate, or lower MOOP limit for purposes of paragraphs (f)(6) and (j) of this section:

(A) *Mandatory MOOP limit:* Above the intermediate MOOP limit and up to and including the mandatory MOOP limit.

(B) *Intermediate MOOP limit:* Above the lower MOOP limit and up to and including the intermediate MOOP limit.

(C) *Lower MOOP limit:* Between $0.00 and up to and including the lower MOOP limit.

(iii) Each MOOP limit CMS sets is rounded to the nearest $50 increment and in cases where the MOOP limit is projected to be exactly in between two $50 increments, CMS rounds to the lower $50 increment.

(iv) For 2022, CMS sets the MOOP limits as follows, subject to the rounding rules in paragraph (f)(4)(iii) of this section and ESRD cost transition schedule in paragraph (f)(4)(vii) of this section:

(A) The mandatory MOOP limit is set at the 95th percentile of projected Medicare FFS beneficiary out-of-pocket spending.

(B) The intermediate MOOP is set at the numeric midpoint of the mandatory and lower MOOP limits.

(C) The lower MOOP limit is set at the 85th percentile of projected Medicare FFS beneficiary out-of-pocket spending.

(v) For 2023 and 2024 or, if later, until the end of the ESRD cost transition, CMS sets the MOOP limits as follows, subject to the rounding rules in paragraph (f)(4)(iii) of this section and ESRD cost transition schedule in paragraph (f)(4)(vii) of this section:

(A) The mandatory MOOP limit does not continue the ESRD cost transition if the prior year's projected 95th percentile (including costs incurred by all Medicare FFS beneficiaries with and without diagnoses of ESRD) is more than two percentiles above or below the projected 95th percentile for the upcoming contract year. Instead, the mandatory MOOP limit increases or decreases by up to 10 percent of the prior year's MOOP limit and the ESRD cost transition schedule resumes at the rate that was scheduled to occur once the prior year's projected 95th percentile remains within the range of two percentiles above or below the projected 95th percentile for the upcoming contract year.

(B) The intermediate MOOP is either maintained at the prior year's limit or updated to the new numeric midpoint if the mandatory or lower MOOP limit changes for the year.

(C) The lower MOOP limit does not continue the ESRD cost transition if the prior year's projected 85th percentile (including costs incurred by all Medicare FFS beneficiaries with and without diagnoses of ESRD) is more than two percentiles above or below the projected 85th percentile for the upcoming contract year. Instead, the lower MOOP limit increases or decreases by up to 10 percent of the prior year's MOOP limit and the ESRD cost transition schedule resumes at the rate that was scheduled to occur once the prior year's projected 85th percentile remains within the range of two percentiles above or below the projected 85th percentile for the upcoming contract year.

(vi) For 2025 or following the ESRD transition schedule in paragraph (f)(4)(vii) of this section and for subsequent years, CMS sets the MOOP limits as follows, subject to the rounding rules in paragraph (f)(4)(iii) of this section:

(A) The prior year's mandatory MOOP limit is maintained for the upcoming contract year if:

(*1*) The prior year's MOOP limit amount is within the range of two percentiles above or below the projected 95th percentile of Medicare FFS beneficiary out-of-pocket spending for the upcoming year incurred by beneficiaries with and without diagnoses of ESRD; and

(*2*) The projected 95th percentile did not increase or decrease for three consecutive years in a row. If the prior year's mandatory MOOP limit is not maintained, CMS increases or decreases the MOOP limit by up to 10 percent of

the prior year's MOOP amount annually until the MOOP limit reaches the projected 95th percentile for the applicable year.

(B) The prior year's intermediate MOOP limit is maintained or updates to the new numeric midpoint if the mandatory or lower MOOP limit changes as outlined in this section.

(C) The prior year's lower MOOP limit is maintained for the upcoming contract year if:

(*1*) The prior year's MOOP limit amount is within the range of two percentiles above or below the projected 85th percentile of Medicare FFS beneficiary out-of-pocket spending for the upcoming year incurred by beneficiaries with and without diagnoses of ESRD; and

(*2*) The projected 85th percentile did not increase or decrease for three consecutive years in a row. If the prior year's lower MOOP limit is not maintained, CMS increases or decreases the MOOP limit by up to 10 percent of the prior year's MOOP amount annually until the MOOP limit reaches the projected 85th percentile for the applicable year.

(vii) For purposes of this section, the *ESRD cost differential* is the difference between, first, for the mandatory MOOP limit, $7,175 and for the lower MOOP limit, $3,360 and second, the projected out-of-pocket costs for beneficiaries using Medicare FFS data (including the costs incurred by beneficiaries with ESRD diagnoses) for each year between 2022 and 2024 or the final year of transition. Subject to the MOOP calculation methodology in paragraphs (f)(4)(iv) through (vi) of this section, CMS transitions to using the most recent, complete Medicare FFS data of beneficiary out-of-pocket spending incurred by beneficiaries with and without diagnoses of ESRD by factoring in a percentage of the ESRD cost differential on the following schedule:

(A) For 2022, CMS factors in 60 percent of the ESRD cost differential.

(B) For 2023 or the next year of ESRD cost transition, CMS factors in 80 percent of the ESRD cost differential.

(C) For 2024 or the final year of the ESRD cost transition and beyond, CMS uses the most recent, complete Medicare FFS data that includes the out-of-pocket costs incurred by beneficiaries with and without diagnoses of ESRD.

(5) With respect to a local PPO plan, the MOOP limits specified under paragraph (f)(4) of this section apply only to use of network providers.

(i) Such local PPO plans must establish a total combined limit on beneficiary out-of-pocket expenditures for basic benefits that are provided in-network and out-of-network that is no greater than the total combined limit applicable to regional plans under § 422.101(d)(3)(ii).

(ii) The type of in-network MOOP limit dictates the type of combined MOOP limit the MA plan may use; MA PPO plans must have the same MOOP type (lower, intermediate, or mandatory) for the in-network MOOP limit and combined limit on in-network and out-of-network out-of-pocket expenditures.

(iii) MA organizations are responsible for tracking out-of-pocket spending incurred by the enrollee, and must alert enrollees and contracted providers when the MOOP limit is reached.

(6) For each year beginning on or after January 1, 2022, a MA organization must establish cost sharing for basic benefits (which may be coinsurance or copayments) that comply with the cost sharing limits in this paragraph (f)(6), which are in addition to any other limits and rules applicable to MA cost sharing, including that MA cost sharing for basic benefits be actuarially equivalent to Medicare FFS cost sharing.

(i)(A) For in-network basic benefits that are not specifically addressed in this paragraph (f)(6)(i) and for out-of-network basic benefits, MA plans may not pay less than 50 percent of the total MA plan financial liability, regardless of the MOOP limit established.

(B) If the MA plan establishes a coinsurance method of cost sharing, then the coinsurance cannot exceed 50 percent.

(C) If the MA plan establishes a copay method of cost sharing, then the copay for out-of-network benefits cannot exceed 50 percent of the average Medicare FFS allowable cost for that service area and the copay for in-network benefits cannot exceed 50 percent of the MA organization's average contracted rate of that benefit (item or service).

(ii)(A) In setting copayment limits, CMS rounds to the nearest whole $5 increment for professional services and nearest whole $1 for inpatient acute and psychiatric and skilled nursing facility cost sharing limits.

(B) For all cases in which the copayment limit is projected to be exactly between two increments, CMS rounds to the lower dollar amount.

(iii)(A) For in-network basic benefits that are professional services, including primary care services, physician specialist services, partial hospitalization, and rehabilitation services, an MA plan may not establish cost sharing that exceeds the limits established by CMS pursuant to this paragraph (f)(6)(ii) for the MOOP limit established by the MA plan.

(B) CMS uses projections of out-of-pocket costs representing beneficiaries with and without diagnoses of ESRD based on the most recent, complete Medicare FFS data for basic benefits that are professional services to set the cost sharing limits.

(C) The professional service cost sharing limits, subject to the rounding rules at paragraph (f)(6)(ii)(A) of this section are as follows:

(*1*) *Mandatory MOOP limit:* 30 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 70 percent of the total MA plan financial liability.

(*2*) *Intermediate MOOP limit:* 40 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 60 percent of the total MA plan financial liability.

(*3*) *Lower MOOP limit:* 50 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 50 percent of the total MA plan financial liability.

(iv)(A) For in-network basic benefits that are inpatient acute and psychiatric services, an MA plan may not establish cost sharing that exceeds the limits established by CMS pursuant to this paragraph (f)(6)(iv) for the MOOP limit established by the MA plan.

(B) The cost sharing limits are set for the following seven inpatient stay scenarios in an inpatient facility for a period for which cost sharing would apply under original Medicare: inpatient hospital acute stay scenarios of 3 days, 6 days, 10 days, and 60 days and psychiatric inpatient hospital stay scenarios of 8 days, 15 days, and 60 days.

(C) CMS sets the inpatient acute and psychiatric cost sharing limits annually using projections of out-of-pocket costs and utilization based on the most recent, complete Medicare FFS data that factors in out-of-pocket costs representing all beneficiaries with diagnoses of ESRD on the transition schedule described in paragraphs (f)(4)(vii)(A) through (D) of this section (without application of the exceptions for MOOP limit calculations in paragraphs (f)(4)(v)(A) and (C) of this section), and may also use patient utilization information from MA encounter data.

(D) The cost sharing limits applicable to inpatient acute and psychiatric services are as follows:

(*1*) *Mandatory MOOP limit:* cost sharing must not exceed 100 percent of estimated Medicare Fee-for-Service cost sharing, including the Part A deductible and related Part B costs, for each length of stay scenario.

(*2*) *Intermediate MOOP limit:* cost sharing must not exceed the numeric mid-point between the cost sharing limits established in paragraphs (f)(6)(iv)(D)(*1*) and (*3*) of this section.

(*3*) *Lower MOOP limit:* cost sharing must not exceed 125 percent of estimated Medicare Fee-for-Service cost sharing, including the Part A deductible and related Part B costs, for each the length of stay scenario. For inpatient acute 60 day length of stays, MA plans that establish a lower MOOP limit have the flexibility to set cost sharing above 125 percent of estimated Medicare Fee-for-Service cost sharing as long as the total cost sharing for the inpatient benefit does not exceed the MOOP limit or cost sharing for inpatient benefits in original Medicare on an per member per month actuarially equivalent basis.

* * * * *

(j) *Cost sharing and actuarial equivalence standards for basic benefits*—(1) *Specific benefits for which cost sharing may not exceed cost sharing under original Medicare.* For each year beginning on or after January 1, 2022, for the following basic benefits, in-network cost sharing established by an MA plan may not exceed the cost sharing required under original Medicare:

(i) Chemotherapy administration services to include chemotherapy/radiation drugs integral to the treatment regimen.

(ii) Renal dialysis services as defined at section 1881(b)(14)(B) of the Act.

(iii) Skilled nursing care, defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under original Medicare, when the MA plan establishes the mandatory MOOP limit; when the MA plan establishes the lower or intermediate MOOP limit, the MA plan may establish cost sharing for the first 20 days of a SNF stay.

(A) Regardless of the MOOP limit established by the MA plan, the per-day cost sharing for days 21 through 100 must not be greater than the projected original Medicare SNF amount.

(B) Total cost sharing for the overall SNF benefit must be no higher than the actuarially equivalent cost sharing for the SNF benefit in original Medicare.

(iv) Home health services (as defined in section 1861(m) of the Act), when the MA plan establishes a mandatory or intermediate MOOP limit; when the MA plan establishes the lower MOOP limit, the MA plan may have cost sharing up to 20 percent of the total MA plan financial liability.

(v) Durable medical equipment (DME), when the MA plan establishes the mandatory MOOP limit; when the MA plan establishes the lower or intermediate MOOP limit, the MA plan may establish cost sharing on specific categories or items of DME as long as the total cost sharing for the overall DME benefit is no higher than the per member per month actuarially equivalent cost sharing for the DME benefit in original Medicare.

(2) *Actuarially equivalent cost sharing for categories of basic benefits in the aggregate.* For each year beginning on or after January 1, 2022, total MA cost sharing for all basic benefits, excluding out of network benefits covered by a regional MA plan, must not exceed cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis.

(i) MA cost sharing for the following specific benefit categories must not exceed the cost sharing for those benefit categories in original Medicare on a per member per month actuarially equivalent basis:

(A) Inpatient hospital acute and psychiatric services, defined as services provided during a covered stay in an inpatient facility during the period for which cost sharing would apply under original Medicare.

(B) Durable medical equipment (DME).

(C) Drugs and biologics covered under Part B of original Medicare (including both chemotherapy/radiation drugs integral to the treatment regimen and other drugs covered under Part B).

(D) Skilled nursing care, defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under original Medicare.

(ii) CMS may extend flexibility for MA plans when evaluating actuarial equivalent cost sharing limits for those service categories to the extent that the per member per month cost sharing limit is actuarially justifiable based on generally accepted actuarial principles and supporting documentation included in the bid, provided that the cost sharing for specific services otherwise satisfies published cost sharing standards.

* * * * *

(m) * * *

(5) * * *

(iii) Provide the information described in paragraphs (m)(1), (2), and (3) and (m)(5)(i) of this section on its website.

■ 14. Section 422.101 by—

■ a. Revising paragraphs (d)(2) and (3), (f)(1) introductory text, and (f)(1)(i) and (iii); and

■ b. Adding paragraph (f)(1)(iv);

■ c. Revising paragraph (f)(2) introductory text; and

■ d. Adding paragraph (f)(3).

The revisions and additions read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(d) * * *

(2) *Catastrophic limit.* For each year beginning on or after January 1, 2022, MA regional plans must establish a catastrophic limit on beneficiary out-of-pocket expenditures for basic benefits that are furnished by in-network providers that is consistent with § 422.100(f)(4) subject to the rounding rules in paragraph (f)(4)(iii) of this section.

(i) The type of catastrophic (in-network) limit dictates the total catastrophic MOOP range for MA regional plans under paragraph (d)(3) of this section, MA regional plans must have the same MOOP type (lower, intermediate, or mandatory) for the in-network MOOP limit and combined catastrophic limit on in-network and out-of-network out-of-pocket expenditures.

(ii) MA organizations are responsible for tracking out-of-pocket spending incurred by the enrollee, and must alert enrollees and contracted providers when the MOOP limit is reached.

(3) *Total catastrophic limit.* For each year beginning on or after January 1, 2022, MA regional plans must establish a total catastrophic limit on beneficiary out-of-pocket expenditures for basic benefits that are provided in-network and out-of-network that is consistent with this paragraph (d)(3).

(i) The total catastrophic limit for both in-network and out-of-network benefits may not be used to increase the limit described in paragraph (d)(2) of this section.

(ii) CMS sets the total catastrophic limit by multiplying the respective in-network MOOP limits by 1.5 for the relevant year, subject to the rounding rules in paragraph (f)(4)(iii) of this section.

(iii) MA organizations are responsible for tracking out-of-pocket spending incurred by the enrollee, and must alert enrollees and contracted providers when the MOOP limit is reached.

* * * * *

(f) * * *

(1) MA organizations offering special needs plans (SNP) must implement an evidence-based model of care with appropriate networks of providers and specialists designed to meet the specialized needs of the plan's targeted enrollees. The MA organization must, with respect to each individual enrolled, do all of the following:

(i) Conduct a comprehensive initial health risk assessment of the individual's physical, psychosocial, and functional needs as well as annual health risk reassessment, using a comprehensive risk assessment tool that CMS may review during oversight activities, and ensure that results from the initial assessment and annual reassessment conducted for each individual enrolled in the plan are addressed in the individual's individualized care plan as required under paragraph (f)(1)(ii) of this section.

* * * * *

(iii) In the management of care, use an interdisciplinary team that includes a team of providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan.

(iv) Provide for face-to-face encounters between each enrollee and a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff on at least an annual basis, beginning within the first 12 month of enrollment, as feasible and with the individual's consent. A face-for-face encounter must be either in person or through a visual, real-time, interactive telehealth encounter.

(2) MA organizations offering SNPs must also develop and implement the following model of care components to assure an effective care management structure:

* * * * *

(3)(i) All MA organizations wishing to offer or continue to offer a SNP will be required to be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. All SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval in accordance with CMS guidance.

(ii) As part of the evaluation and approval of the SNP model of care, NCQA must evaluate whether goals were fulfilled from the previous model of care.

(A) Plans must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment the previous MOC's goals.

(B) Plans submitting an initial model of care must provide relevant information pertaining to the MOC's goals for review and approval.

(C) If the SNP model of care did not fulfill the previous MOC's goals, the plan must indicate in the MOC submission how it will achieve or revise the goals for the plan's next MOC.

(iii) Each element of the model of care of a plan must meet a minimum benchmark score of 50 percent, and a plan's model of care will only be approved if each element of the model of care meets the minimum benchmark.

■ 15. Section 422.102 is amended—

■ a. In paragraph (a)(4) by removing the phrase ''only as a mandatory'' and adding in its place the phrase ''for Part A and B benefits only as a mandatory''; and

■ b. Adding paragraphs (a)(5) and (6) and (f).

The revisions and additions read as follows:

§ 422.102 Supplemental benefits.

(a) * * *

(5) An MA plan may reduce the cost sharing for items and services that are not basic benefits only as a mandatory supplemental benefit.

(6) An MA plan may offer mandatory supplemental benefits in the following forms:

(i) Reductions in cost sharing through the use of reimbursement, through a debit card or other means, for cost sharing paid for covered benefits. Reimbursements must be limited to the specific plan year.

(ii) Use of a uniform dollar amount as a maximum plan allowance for a package of supplemental benefits, including reductions in cost sharing or coverage of specific items and services, available to enrollees on a uniform basis for enrollee use for any supplemental benefit in the package. Allowance must be limited to the specific plan year.

* * * * *

(f) *Special supplemental benefits for the chronically ill (SSBCI)*—(1) *Requirements*—(i) *Chronically-ill enrollee.* (A) A chronically ill enrollee is an individual enrolled in the MA plan who has one or more comorbid and medically complex chronic conditions that meet all of the following:

(*1*) Is life threatening or significantly limits the overall health or function of the enrollee;

(*2*) Has a high risk of hospitalization of other adverse health outcomes; and

(*3*) Requires intensive care coordination.

(B) CMS may publish a non-exhaustive list of conditions that are medically complex chronic conditions that are life threatening or significantly limit the overall health or function of an individual.

(ii) *SSBCI definition.* A special supplemental benefit for the chronically ill (SSBCI) is a supplemental benefit that has, with respect to a chronically ill enrollee, a reasonable expectation of improving or maintaining the health or overall function of the enrollee; an SSBCI that meets this standard may also include a benefit that is not primarily health related, as defined in § 422.100(c)(2)(ii).

(2) *Offering SSBCI.* (i) An MA plan may offer SSBCI to a chronically ill enrollee only as a mandatory supplemental benefit.

(ii) Upon approval by CMS, an MA plan may offer SSBCI that are not uniform for all chronically ill enrollees in the plan.

(iii) An MA plan may consider social determinants of health as a factor to help identify chronically ill enrollees whose health or overall function or could be improved or maintained with SSBCI. An MA plan may not use social determinants of health as the sole basis for determining eligibility for SSBCI.

(3) *Plan responsibilities.* An MA plan offering SSBCI must do all of the following:

(i) Must have written policies for determining enrollee eligibility and must document its determination that an enrollee is a chronically ill enrollee based on the definition in paragraph (f)(1)(i) of this section.

(ii) Make information and documentation related to determining enrollee eligibility available to CMS upon request.

(iii) Must have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI and must document this criteria.

(iv) Document each determination that an enrollee is eligible to receive an SSBCI and make this information available to CMS upon request.

§ 422.110 [Amended]

■ 16. Section 422.110 is amended in paragraph (b) by removing the phrase ''An MA organization'' and adding in its place the phrase ''For coverage before January 1, 2021, an MA organization''.

■ 17. Section 422.111 is amended by—

■ a. Removing paragraph (b)(12);

■ b. Revising paragraphs (h)(1)(i), (ii) and (iii); and

■ c. Adding paragraphs (h)(1)(iv) and (v), (j), and (k).

The revisions and additions read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(h) * * *

(1) * * *

(i) Is open at least from 8:00 a.m. to 8:00 p.m. in all service areas served by the Part C plan.

(ii) At a minimum, provides customer telephone service access, in accordance with the following business practices:

(A) Limits average hold time to no longer than 2 minutes. The hold time is defined as the time spent on hold by callers following the interactive voice response (IVR) system, touch-tone response system, or recorded greeting, before reaching a live person.

(B) Answers 80 percent of incoming calls within 30 seconds after the Interactive Voice Response (IVR), touch-tone response system, or recorded greeting interaction.

(C) Limits the disconnect rate of all incoming calls to no higher than 5 percent. The disconnect rate is defined as the number of calls unexpectedly dropped divided by the total number of calls made to the customer call center.

(iii)(A) Provides interpreters for non-English speaking and limited English proficient (LEP) individuals.

(B) Interpreters must be available within 8 minutes of reaching the customer service representative and be made available at no cost to the caller.

(iv) Responds to TTY-to-TTY calls as defined in 47 CFR part 64, subpart F, in accordance with the mandatory minimum standards delineated in 47 CFR 64.604.

(v) Provides effective real-time communication with individuals using auxiliary aids and services, including TTYs and all forms of Federal Communication Commission-approved telecommunications relay systems, when using automated-attendant systems. See 28 CFR 35.161 and 36.303(d).

* * * * *

(j) *Safe disposal of certain prescription drugs.* Information regarding the safe disposal of prescription drugs that are controlled substances and drug takeback programs must be provided in the case of an individual enrolled under an MA plan who is furnished an in-home health risk assessment on or after January 1, 2021.

(1) As part of the in-home health risk assessment, the enrollees must be furnished written supporting materials describing how to safely dispose of medications that are controlled substances as well as a verbal summary when possible. The written information furnished to enrollees about the safe disposal of medications and takeback programs must include the following information for enrollees:

(i) Unused medications should be disposed of as soon as possible.

(ii) The US Drug Enforcement Administration (DEA) allows unused prescription medications to be mailed back to pharmacies and other authorized sites using packages made available at such pharmacies or such other locations.

(iii) Community take back sites are the preferred method of disposing of unused controlled substances.

(iv) Location of take back sites available in the MA plan service area where the enrollee resides or that are nearest to the enrollee's residence.

(v) Instructions on how to safely dispose of medications in household trash or of cases when a medication can be safely flushed. Include instructions on removing personal identification information when disposing of prescription containers.

(vi) Include a web link to the information available on the United States Department of Health and Human Services website identifying methods for the safe disposal of drugs available at the following web address: *www.hhs.gov/opioids/prevention/safely-dispose-drugs/index.html*

(k) *Claims information.* MA organizations must furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under this part.

(1) *Information requirements for the reporting period.* Claims data elements presented on the explanation of benefits must include all of the following for the reporting period:

(i) The descriptor and billing code for the item or service billed by the provider, and the corresponding amount billed.

(ii) The total cost approved by the plan for reimbursement.

(iii) The share of total cost paid for by the plan.

(iv) The share of total cost for which the enrollee is liable.

(2) *Information requirements for year-to-date totals.* Claims data elements presented on the explanation of benefits must include specific year-to-date totals as follows:

(i) The cumulative amount billed by all providers.

(ii) The cumulative total costs approved by the plan.

(iii) The cumulative share of total cost paid for by the plan.

(iv) The cumulative share of total cost for which the enrollee is liable.

(v) The amount an enrollee has incurred toward the MOOP limit, as applicable.

(vi) The amount an enrollee has incurred toward the deductible, as applicable.

(3) *Additional information requirements.* (i) Each explanation of benefits must include clear contact information for enrollee customer service.

(ii) Each explanation of benefits must include instructions on how to report fraud.

(iii) Each EOB that includes a denied claim must clearly identify the denied claim and provide information about enrollee appeal rights, but the EOB does not replace the notice required by §§ 422.568 and 422.570.

(4) *Reporting cycles for explanation of benefits.* MA organizations must send an explanation of benefits on either a monthly cycle or a quarterly cycle with per-claim notifications.

(i) A monthly explanation of benefits must include all claims processed in the prior month and, for each claim, the information in paragraphs (k)(1) and (2) of this section as of the last day of the prior month.

(A) The monthly explanation of benefits must be sent before the end of each month that follows the month a claim was filed.

(B) [Reserved]

(ii) A quarterly explanation of benefits must include all claims processed in the quarter and, for each claim, the information in paragraphs (k)(1) and (2) of this section as of the last day of the quarter; a per-claim notification must include all claims processed in the prior month and, for each claim, the information specified in paragraph (k)(1) of this section as of the last day of the prior month.

(A) MA organizations that send the explanation of benefits on a quarterly cycle with per-claim notifications must send the quarterly explanation of benefits before the end of each month that follows the quarter in which a claim was filed.

(B) MA organizations that send the explanation of benefits on a quarterly cycle with per-claim notifications must send the per-claim notification before the end of each month that follows the month in which a claim was filed.

■ 18. Section 422.113 is amended by—

■ a. Revising paragraph (b)(2)(v); and

■ b. Adding paragraph (b)(2)(vi).

The revision and addition read as follows:

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

* * * * *

(b) * * *

(2) * * *

(v) For each year beginning on or after January 1, 2022, with a dollar limit on emergency services including post-stabilization services costs for enrollees that is the lower of—

(A) The cost sharing established by the MA plan if the emergency services

were provided through the MA organization; or

(B) A maximum cost sharing limit permitted per visit that corresponds to the MA plan MOOP limit as follows:

(*1*) $115 for MA plans with a mandatory MOOP limit.

(*2*) $130 for MA plans with an intermediate MOOP limit.

(*3*) $150 for MA plans with a lower MOOP limit.

(vi) For each year beginning on or after January 1, 2022, with a cost sharing limit on urgently needed services that does not exceed the limits specified for professional services in § 422.100(f)(6)(iii).

* * * * *

■ 19. Section 422.116 is added to read as follows:

§ 422.116 Network adequacy.

(a) *General rules*—(1) *Access.* A network-based MA plan, as described in § 422.114(a)(3)(ii) but not including MSA plans, must demonstrate that it has an adequate contracted provider network that is sufficient to provide access to covered services in accordance with access standards described in section 1852(d)(1) of the Act and in §§ 422.112(a) and 422.114(a)(1) and by meeting the standard in paragraph (a)(2) of this section. When required by CMS, an MA organization must attest that it has an adequate network for access and availability of a specific provider or facility type that CMS does not independently evaluate in a given year.

(2) *Standards.* An MA plan must meet maximum time and distance standards and contract with a specified minimum number of each provider and facility-specialty type.

(i) Each contract provider type must be within maximum time and distance of at least one beneficiary in order to count toward the minimum number.

(ii) The minimum number criteria and the time and distance criteria vary by the county type.

(3) *Applicability of MA network adequacy criteria.* (i) The following providers and facility types do not count toward meeting network adequacy criteria:

(A) Specialized, long-term care, and pediatric/children's hospitals.

(B) Providers that are only available in a residential facility.

(C) Providers and facilities contracted with the organization only for its commercial, Medicaid, or other products.

(ii) For the facility type of outpatient dialysis, hospital-based dialysis may count in network adequacy criteria.

(4) *Annual updates by CMS.* CMS annually updates and makes the following available:

(i) A Health Service Delivery (HSD) Reference file that identifies the following:

(A) All minimum provider and facility number requirements.

(B) All provider and facility time and distance standards.

(C) Ratios established in paragraph (e) of this section in advance of network reviews for the applicable year.

(ii) A Provider Supply file that lists available providers and facilities and their corresponding office locations and specialty types.

(A) The Provider Supply file is updated annually based on information in the Integrated Data Repository (IDR), which has comprehensive claims data, and information from public sources.

(B) CMS may also update the Provider Supply file based on findings from validation of provider information submitted on Exception Requests to reflect changes in the supply of health care providers and facilities.

(b) *Provider and facility-specialty types.* The provider and facility-specialty types to which the network adequacy evaluation under this section applies are specified in this paragraph (b).

(1) *Provider-specialty types.* The provider-specialty types are as follows:

(i) Primary Care.

(ii) Allergy and Immunology.

(iii) Cardiology.

(iv) Chiropractor.

(v) Dermatology.

(vi) Endocrinology.

(vii) ENT/Otolaryngology.

(viii) Gastroenterology.

(ix) General Surgery.

(x) Gynecology, OB/GYN.

(xi) Infectious Diseases.

(xii) Nephrology.

(xiii) Neurology.

(xiv) Neurosurgery.

(xv) Oncology—Medical, Surgical.

(xvi) Oncology—Radiation/Radiation Oncology.

(xvii) Ophthalmology.

(xviii) Orthopedic Surgery.

(xix) Physiatry, Rehabilitative Medicine.

(xx) Plastic Surgery.

(xxi) Podiatry.

(xxii) Psychiatry.

(xxiii) Pulmonology.

(xxiv) Rheumatology.

(xxv) Urology.

(xxvi) Vascular Surgery.

(xxvii) Cardiothoracic Surgery.

(2) *Facility-specialty types.* The facility specialty types are as follows:

(i) Acute Inpatient Hospitals.

(ii) Cardiac Surgery Program.

(iii) Cardiac Catheterization Services.

(iv) Critical Care Services—Intensive Care Units (ICU).

(v) Outpatient Dialysis (including hospital-based outpatient dialysis).

(vi) Surgical Services (Outpatient or ASC).

(vii) Skilled Nursing Facilities.

(viii) Diagnostic Radiology.

(ix) Mammography.

(x) Physical Therapy.

(xi) Occupational Therapy.

(xii) Speech Therapy.

(xiii) Inpatient Psychiatric Facility Services.

(xiv) Outpatient Infusion/Chemotherapy.

(3) *Removal of a provider or facility-specialty type.* CMS may remove a specialty or facility type from the network adequacy evaluation for a particular year by not including the type in the annual publication of the HSD reference file.

(c) *County type designations.* Counties are designated as a specific type using the following population size and density parameters:

(1) *Large metro.* A large metro designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 1,000,000 persons with a population density greater than or equal to 1,000 persons per square mile.

(ii) A population size greater than or equal to 500,000 and less than or equal to 999,999 persons with a population density greater than or equal to 1,500 persons per square mile.

(iii) Any population size with a population density of greater than or equal to 5,000 persons per square mile.

(2) *Metro.* A metro designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 1,000,000 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 999.9 persons per square mile.

(ii) A population size greater than or equal to 500,000 persons and less than or equal to 999,999 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 1,499.9 persons per square mile.

(iii) A population size greater than or equal to 200,000 persons and less than or equal to 499,999 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 4,999.9 persons per square mile.

(iv) A population size greater than or equal to 50,000 persons and less than or equal to 199,999 persons with a population density greater than or equal

to 100 persons per square mile and less than or equal to 4999.9 persons per square mile.

(v) A population size greater than or equal to 10,000 persons and less than or equal to 49,999 persons with a population density greater than or equal to 1,000 persons per square mile and less than or equal to 4999.9 persons per square mile.

(3) *Micro.* A micro designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 50,000 persons and less than or equal to 199,999 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 99.9 persons per square mile.

(ii) A population size greater than or equal to 10,000 persons and less than or equal to 49,999 persons with a population density greater than or equal to 50 persons per square mile and less than 999.9 persons per square mile.

(4) *Rural.* A rural designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 10,000 persons and less than or equal to 49,999 persons with a population density of greater than or equal to 10 persons per square mile and less than or equal to 49.9 persons per square mile.

(ii) A population size less than 10,000 persons with a population density greater than or equal 50 persons per square mile and less than or equal to 999.9 persons per square mile.

(5) *Counties with extreme access considerations (CEAC).* For any population size with a population density of less than 10 persons per square mile.

(d) *Maximum time and distance standards*—(1) *General rule.* CMS determines and annually publishes maximum time and distance standards for each combination of provider or facility specialty type and each county type in accordance with paragraphs (d)(2) and (3) of this section.

(i) Time and distance metrics measure the relationship between the approximate locations of beneficiaries and the locations of the network providers and facilities.

(ii) [Reserved]

(2) *By county designation.* The following base maximum time (in minutes) and distance (in miles) standards apply for each county type designation, unless modified through customization as described in paragraph (d)(3) of this section.

TABLE 1 TO PARAGRAPH (d)(2)

Provider/Facility Type	Large Metro		Metro		Micro		Rural		CEAC	
	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance
Primary Care	10	5	15	10	30	20	40	30	70	60
Allergy and Immunology	30	15	45	30	80	60	90	75	125	110
Cardiology	20	10	30	20	50	35	75	60	95	85
Chiropractor	30	15	45	30	80	60	90	75	125	110
Dermatology	20	10	45	30	60	45	75	60	110	100
Endocrinology	30	15	60	40	100	75	110	90	145	130
ENT/Otolaryngology	30	15	45	30	80	60	90	75	125	110
Gastroenterology	20	10	45	30	60	45	75	60	110	100
General Surgery	20	10	30	20	50	35	75	60	95	85
Gynecology, OB/GYN	30	15	45	30	80	60	90	75	125	110
Infectious Diseases	30	15	60	40	100	75	110	90	145	130
Nephrology	30	15	45	30	80	60	90	75	125	110
Neurology	20	10	45	30	60	45	75	60	110	100
Neurosurgery	30	15	60	40	100	75	110	90	145	130
Oncology—Medical, Surgical	20	10	45	30	60	45	75	60	110	100
Oncology—Radiation/Radiation Oncology	30	15	60	40	100	75	110	90	145	130
Ophthalmology	20	10	30	20	50	35	75	60	95	85
Orthopedic Surgery	20	10	30	20	50	35	75	60	95	85
Physiatry, Rehabilitative Medicine	30	15	45	30	80	60	90	75	125	110
Plastic Surgery	30	15	60	40	100	75	110	90	145	130
Podiatry	20	10	45	30	60	45	75	60	110	100
Psychiatry	20	10	45	30	60	45	75	60	110	100
Pulmonology	20	10	45	30	60	45	75	60	110	100
Rheumatology	30	15	60	40	100	75	110	90	145	130
Urology	20	10	45	30	60	45	75	60	110	100
Vascular Surgery	30	15	60	40	100	75	110	90	145	130
Cardiothoracic Surgery	30	15	60	40	100	75	110	90	145	130
Acute Inpatient Hospitals	20	10	45	30	80	60	75	60	110	100
Cardiac Surgery Program	30	15	60	40	160	120	145	120	155	140
Cardiac Catheterization Services	30	15	60	40	160	120	145	120	155	140
Critical Care Services—Intensive Care Units (ICU)	20	10	45	30	160	120	145	120	155	140

TABLE 1 TO PARAGRAPH (d)(2)—Continued

Provider/Facility Type	Large Metro		Metro		Micro		Rural		CEAC	
	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance
Outpatient Dialysis	20	10	45	30	65	50	55	50	100	90
Surgical Services (Outpatient or ASC)	20	10	45	30	80	60	75	60	110	100
Skilled Nursing Facilities	20	10	45	30	80	60	75	60	95	85
Diagnostic Radiology	20	10	45	30	80	60	75	60	110	100
Mammography	20	10	45	30	80	60	75	60	110	100
Physical Therapy	20	10	45	30	80	60	75	60	110	100
Occupational Therapy	20	10	45	30	80	60	75	60	110	100
Speech Therapy	20	10	45	30	80	60	75	60	110	100
Inpatient Psychiatric Facility Services	30	15	70	45	100	75	90	75	155	140
Outpatient Infusion/Chemotherapy	20	10	45	30	80	60	75	60	110	100

(3) *By customization.* CMS may set maximum time and distance standards for provider or facility types for specific counties by customization in accordance with the following rules:

(i) CMS maps provider location data from the Provider Supply file against its MA Medicare Sample Census (which provides MA enrollee population distribution data) or uses claims data to identify the distances beneficiaries travel according to the usual patterns of care for the county.

(ii) CMS identifies the distance at which 90 percent of the population would have access to at least one provider or facility in the applicable specialty type.

(iii) The resulting distance is then rounded up to the next multiple of 5, and a multiplier specific to the county designation is applied to determine the analogous maximum time.

(iv) Customization may only be used to increase the base time and distance standards specified in paragraph (d)(2) of this section and may not be used to decrease the base time and distance standards.

(4) *Percentage of beneficiaries residing within maximum time and distance standards.* MA plans must ensure both of the following:

(i) At least 85 percent of the beneficiaries residing in micro, rural, or CEAC counties have access to at least one provider/facility of each specialty type within the published time and distance standards.

(ii) At least 90 percent of the beneficiaries residing in large metro and metro counties have access to at least one provider/facility of each specialty type within the published time and distance standards.

(5) *MA telehealth providers.* An MA plan receives a 10 percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the applicable provider specialty type and county when the plan includes one or more telehealth providers that provide additional telehealth benefits, as defined in § 422.135, in its contracted networks for the following provider specialty types:

(i) Dermatology.

(ii) Psychiatry.

(iii) Cardiology.

(iv) Neurology.

(v) Otolaryngology.

(6) *State Certificate of Need (CON) laws.* In a state with CON laws, or other state imposed anti-competitive restrictions that limit the number of providers or facilities in the state or a county in the state, CMS may award the MA organization a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected providers and facilities in paragraph (b) of this section or, where appropriate, specifically customize the base time and distance standards based on the effects of CON laws.

(e) *Minimum number standard.* CMS annually determines the minimum number standard for each provider and facility-specialty type as follows:

(1) *General rule.* The provider or facility must—

(i) Be within the maximum time and distance of at least one beneficiary in order to count towards the minimum number standard (requirement); and

(ii) Not be a telehealth-only provider.

(2) *Minimum number requirement for provider and facility-specialty types.* The minimum number for provider and facility-specialty types are as follows:

(i) For provider-specialty types described in paragraph (b)(1) of this section, CMS calculates the minimum number as specified in paragraph (e)(3) of this section.

(ii) For facility-specialty types described in paragraph (b)(2)(i) of this section, CMS calculates the minimum number as specified in paragraph (e)(3) of this section.

(iii) For facility-specialty types described in paragraphs (b)(2)(ii) through (xiv) of this section, the minimum requirement number is 1.

(3) *Determination of the minimum number of for certain provider and facility-specialty types.* For specialty types in paragraphs (b)(1) and (b)(2)(i) of this section, CMS multiplies the minimum ratio by the number of beneficiaries required to cover, divides the resulting product by 1,000, and rounds it up to the next whole number.

(i)(A) The minimum ratio for provider specialty types represents the minimum number of providers per 1,000 beneficiaries.

(B) The minimum ratio for facility specialty type specified in paragraph (b)(2)(i) of this section (acute inpatient hospital) represents the minimum number of beds per 1,000 beneficiaries.

(C) The minimum ratios are as follows:

TABLE 2 TO PARAGRAPH (e)(3)(i)(C)

Minimum ratio	Large metro	Metro	Micro	Rural	CEAC
Primary Care	1.67	1.67	1.42	1.42	1.42
Allergy and Immunology	0.05	0.05	0.04	0.04	0.04
Cardiology	0.27	0.27	0.23	0.23	0.23
Chiropractor	0.10	0.10	0.09	0.09	0.09
Dermatology	0.16	0.16	0.14	0.14	0.14
Endocrinology	0.04	0.04	0.03	0.03	0.03
ENT/Otolaryngology	0.06	0.06	0.05	0.05	0.05
Gastroenterology	0.12	0.12	0.10	0.10	0.10
General Surgery	0.28	0.28	0.24	0.24	0.24
Gynecology, OB/GYN	0.04	0.04	0.03	0.03	0.03
Infectious Diseases	0.03	0.03	0.03	0.03	0.03
Nephrology	0.09	0.09	0.08	0.08	0.08
Neurology	0.12	0.12	0.10	0.10	0.10
Neurosurgery	0.01	0.01	0.01	0.01	0.01
Oncology—Medical, Surgical	0.19	0.19	0.16	0.16	0.16
Oncology—Radiation/Radiation Oncology	0.06	0.06	0.05	0.05	0.05
Ophthalmology	0.24	0.24	0.20	0.20	0.20
Orthopedic Surgery	0.20	0.20	0.17	0.17	0.17
Physiatry, Rehabilitative Medicine	0.04	0.04	0.03	0.03	0.03
Plastic Surgery	0.01	0.01	0.01	0.01	0.01
Podiatry	0.19	0.19	0.16	0.16	0.16
Psychiatry	0.14	0.14	0.12	0.12	0.12
Pulmonology	0.13	0.13	0.11	0.11	0.11
Rheumatology	0.07	0.07	0.06	0.06	0.06
Urology	0.12	0.12	0.10	0.10	0.10
Vascular Surgery	0.02	0.02	0.02	0.02	0.02
Cardiothoracic Surgery	0.01	0.01	0.01	0.01	0.01
Acute Inpatient Hospitals	12.2	12.2	12.2	12.2	12.2

(ii)(A) *Number of beneficiaries required to cover.* (*1*) The number of beneficiaries required to cover is calculated by multiplying the 95th percentile base population ratio by the total number of Medicare beneficiaries residing in a county.

(*2*) CMS uses its MA State/County Penetration data to calculate the total beneficiaries residing in a county.

(B) *95th percentile base population ratio.* (*1*) The 95th percentile base population ratio is:

(*i*) Calculated annually for each county type and varies over time as MA market penetration and plan enrollment change across markets; and

(*ii*) Represents the proportion of Medicare beneficiaries enrolled in the 95th percentile MA plan (that is, 95 percent of plans have enrollment lower than this level).

(*2*) CMS calculates the 95th percentile base population ratio as follows:

(*i*) Uses its most recent List of PFFS Network Counties to exclude any PFFS plans in non-networked counties from the calculation at the county-type level.

(*ii*) Uses its most recent MA State/County Penetration data to determine the number of eligible Medicare beneficiaries in each county.

(*iii*) Uses its Monthly MA Enrollment By State/County/Contract data to determine enrollment at the contract ID and county level, including only enrollment in RPPO, LPPO, HMO, HMO/POS, healthcare prepayment plans under section 1833 of the Act, and network PFFS plan types.

(*iv*) Calculates penetration at the contract ID and county level by dividing the number of enrollees for a given contract ID and county by the number of eligible beneficiaries in that county.

(*v*) Groups counties by county designation to determine the 95th percentile of penetration among MA plans for each county type.

(f) *Exception requests.* (1) An MA plan may request an exception to network adequacy criteria in paragraphs (b) through (e) of this section when both of the following occur:

(i) Certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type.

(ii) The MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care.

(2) In evaluating exception requests, CMS considers whether—

(i) The current access to providers and facilities is different from the HSD reference and Provider Supply files for the year;

(ii) There are other factors present, in accordance with § 422.112(a)(10)(v), that demonstrate that network access is consistent with or better than the original Medicare pattern of care; and

(iii) Approval of the exception is in the best interests of beneficiaries.

■ 20. Section 422.134 is revised to read as follows:

§ 422.134 Reward and incentive programs.

(a) *Definitions.* As used in this section, the following definitions are applicable:

Incentive item means the same things as reward item.

Incentive(s), R&I, and *rewards and incentives* mean the same things as reward(s).

Incentive(s) program, Reward(s) program, and *R&I program* means the same thing as rewards and incentives program.

Qualifying individual in the context of a plan-covered health benefit means any plan enrollee who would qualify for coverage of the benefit and satisfies the plan criteria to participate in the target activity. In the context of a non-plan-covered health benefit it means any plan enrollee who satisfies the plan criteria to participate in the target activity.

Reward and incentive program is a program offered by an MA plan to qualifying individuals to voluntarily perform specified target activities in exchange for reward items.

Reward item (or incentive item) means the item furnished to a qualifying individual who performs a target

activity as specified by the plan in the reward program.

Target activity means the activity for which the reward is provided to the qualifying individual by the MA plan.

(b) *Offering an R&I program.* An MA plan may offer R&I program(s) consistent with the requirements of this section.

(c) *Target activities.* (1) A target activity in an R&I program must meet all of the following:

(i) Directly involve the qualifying individual and performance by the qualifying individual.

(ii) Be specified, in detail, as to the level of completion needed in order to qualify for the reward item.

(iii) Be health-related by doing at least one of the following:

(A) Promoting improved health.

(B) Preventing injuries and illness,

(C) Promoting the efficient use of health care resources.

(2) The target activity in an R&I program must not do any of the following:

(i) Be related to Part D benefits.

(ii) Discriminate against enrollees. To assure that anti-discrimination requirements are met, an MA organization, in providing a rewards and incentives program, must comply with paragraph (f)(1) of this section and all the following:

(A) Uniformly offer any qualifying individual the opportunity to participate in the target activity.

(B) Provide accommodations to otherwise qualifying individuals who are unable to perform the target activity in a manner that satisfies the intended goal of the target activity.

(C) Not design a program based on the achievement of a health status measurement.

(d) *Reward items.* (1) The reward item for a target activity must meet all of the following:

(i) Be offered uniformly to any qualifying individual who performs the target activity.

(ii) Be a direct tangible benefit to the qualifying individual who performs the target activity.

(iii) Be provided, such as through transfer of ownership or delivery, to the enrollee in the contract year in which the activity is completed, regardless if the enrollee is likely to use the reward item after the contract year.

(2) The reward item for a target activity must not:

(i) Be offered in the form of cash, cash equivalents, or other monetary rebates (including reduced cost sharing or premiums). An item is classified as a cash equivalent if it either:

(A) Is convertible to cash (such as a check); or

(B) Can be used like cash (such as a general purpose debit card).

(ii) Have a value that exceeds the value of the target activity itself.

(iii) Involve elements of chance.

(3) Permissible reward items for a target activity may be reward items that:

(i) Consist of ''points'' or ''tokens'' that can be used to acquire tangible items.

(ii) Are offered in the form of a gift card that can be redeemed only at specific retailers or retail chains or for a specific category of items or services.

(e) *Marketing and communication requirements.* An MA organization that offers an R&I program must comply with all marketing and communications requirements in subpart V of this part.

(f) *R&I disclosure.* MA organization must make information available to CMS upon request about the form and manner of any rewards and incentives programs it offers and any evaluations of the effectiveness of such programs.

(g) *Miscellaneous.* (1) The MA organization's reward and incentive program must comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil monetary penalty prohibiting inducements to beneficiaries. Additionally all MA program anti-discrimination prohibitions continue to apply. The R&I program may not discriminate against enrollees based on race, national origin, including limited English proficiency, gender, disability, chronic disease, whether a person resides or receives services in an institutional setting, frailty, health status, or other prohibited basis.

(2) Failure to comply with R&I program requirements may result in a violation of one or more of the basis for sanction at § 422.752(a).

(3) The reward and incentive program is classified as a non-benefit expense in the plan bid.

(i) If offering a reward and incentive program, the MA organization must include all costs associated with the reward and incentive program as an administrative cost and non-benefit expense in the bid for the year in which the reward and incentive program operates.

(ii) Disputes on rewards and incentives must be treated as a grievance under § 422.564.

(4) A reward and incentive program may not be changed mid-year.

■ 21. Section 422.162 is amended—

■ a. In paragraph (a) by adding a definition for ''Tukey outer fence outliers'' in alphabetical order;

■ b. By revising paragraphs (b)(3)(iv)(A) and (B); and

■ c. By adding paragraph (b)(4).

The additions and revisions read as follows:

§ 422.162 Medicare Advantage Quality Rating System.

(a) * * *

Tukey outer fence outliers are measure scores that are below a certain point (first quartile − 3.0 × (third quartile − first quartile)) or above a certain point (third quartile + 3.0 × (third quartile − first quartile)).

(b) * * *

(3) * * *

(iv) * * *

(A)(*1*) For the first year after consolidation, CMS uses enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except survey-based measures and call center measures. The survey-based measures would use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures would use average enrollment during the study period.

(*2*) For contract consolidations approved on or after January 1, 2021, if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 422.164(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

(B)(*1*) For the second year after consolidation, CMS uses the enrollment-weighted measure scores using the July enrollment of the measurement year of the consumed and surviving contracts for all measures except for HEDIS, CAHPS, and HOS. HEDIS and HOS measure data are scored as reported. CMS ensures that the CAHPS survey sample includes enrollees in the sample frame from both the surviving and consumed contracts.

(*2*) For contract consolidations approved on or after January 1, 2021, for all measures except HEDIS, CAHPS, and HOS if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 422.164(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

* * * * *

(4) *Quality bonus payment ratings.* (i) For contracts that receive a numeric Star Rating, the final quality bonus payment (QBP) rating for the contract is released in April of each year for the following contract year. The QBP rating is the contract's highest rating from the Star Ratings published by CMS in October of the calendar year that is 2 years before

the contract year to which the QBP rating applies.

(ii) The contract QBP rating is applied to each plan benefit package offered under the contract.

* * * * *

■ 22. Section 422.164 is amended by revising paragraph (g)(1)(iii)(A) to read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(A)(*1*) The data submitted for the Timeliness Monitoring Project (TMP) or audit that aligns with the Star Ratings year measurement period is used to determine the scaled reduction.

(*2*) For contract consolidations approved on or after January 1, 2021, if there is a contract consolidation as described at § 422.162(b)(3), the TMP or audit data are combined for the consumed and surviving contracts before the methodology provided in paragraphs (g)(1)(iii)(B) through (O) of this section is applied.

* * * * *

■ 23. Section 422.166 is amended—

■ a. By revising paragraph (a)(2)(i);

■ b. By adding paragraph (d)(2)(vi);

■ c. In paragraphs (e)(1)(iii) and (iv) by removing the phrase ''weight of 2'' and adding in its place ''weight of 4''; and

■ d. By adding a sentence to the end of paragraph (i)(8).

The revision and additions read as follows:

§ 422.166 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data, and a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next. Prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

* * * * *

(d) * * *

(2) * * *

(vi) The QBP ratings for contracts that do not have sufficient data to calculate and assign ratings and do not meet the definition of low enrollment or new MA plans at § 422.252 are assigned as follows:

(A) For a new contract under an existing parent organization that has other MA contract(s) with numeric Star Ratings in November when the preliminary QBP ratings are calculated for the contract year that begins 14 months later, the QBP rating assigned is the enrollment-weighted average highest rating of the parent organization's other MA contract(s) that are active as of the April when the final QBP ratings are released under § 422.162(b)(4). The Star Ratings used in this calculation are the rounded stars (to the whole or half star) that are publicly displayed on *www.medicare.gov.*

(B) For a new contract under a parent organization that does not have other MA contract(s) with numeric Star Ratings in November when the preliminary QBP ratings are calculated for the contract year that begins 14 months later, the MA Star Ratings for the previous 3 years are used and the QBP rating is the enrollment-weighted average of the MA contract(s)'s highest ratings from the most recent year rated for that parent organization.

(*1*) The Star Ratings had to be publicly reported on *www.medicare.gov.*

(*2*) The Star Ratings used in this calculation are rounded to the whole or half star.

(C) The November enrollment is used in the enrollment-weighted calculations for the year the Star Ratings are released.

(D) The QBP ratings are updated for any changes in a contract's parent organization that are reflected in CMS records prior to the release of the final QBP ratings in April of each year.

(E) Once the QBP ratings are finalized in April of each year for the following contract year, no additional parent organization changes are used for purposes of assigning QBP ratings.

* * * * *

(i) * * *

(8) * * * Missing data includes data where there is a data integrity issue as defined at § 422.164(g)(1).

* * * * *

■ 24. Section 422.220 is revised to read as follows:

§ 422.220 Exclusion of payment for basic benefits furnished under a private contract.

(a) Unless otherwise authorized in paragraph (b) or (c) of this section, an MA organization may not pay, directly or indirectly, on any basis, for basic benefits furnished to a Medicare enrollee by a physician (as defined in paragraphs (1), (2), (3), and (4) of section 1861(r) of the Act) or other practitioner (as defined in section 1842(b)(18)(C) of the Act) who has filed with the Medicare contractor an affidavit promising to furnish Medicare-covered services to Medicare beneficiaries only through private contracts under section 1802(b) of the Act with the beneficiaries.

(b) An MA organization must pay for emergency or urgently needed services furnished by a physician or practitioner described in paragraph (a) of this section who has not signed a private contract with the beneficiary.

(c) An MA organization may make payment to a physician or practitioner described in paragraph (a) of this section for services that are not basic benefits but are provided to a beneficiary as a supplemental benefit consistent with § 422.102.

■ 25. Section 422.252 is amended by revising the definition of ''New MA plan'' to read as follows:

§ 422.252 Terminology.

* * * * *

New MA plan means a plan that meets the following:

(1) Offered under a new MA contract.

(2) Offered under an MA contract that is held by a parent organization defined at § 422.2 that has not had an MA contract in the prior 3 years. For purposes of this definition, the parent organization is identified as of April of the calendar year before the payment year to which the final QBP rating applies, and contracts associated with that parent organization are also evaluated using contracts in existence as of April of the 3 calendar years before the payment year to which the final QBP rating applies. Under our current policy, we identify the parent organization for each MA contract in April of each year and then whether any MA contracts have been held by that parent organization in the immediately preceding 3 years to determine if the parent organization meets the 3-year standard.

* * * * *

§ 422.258 [Amended]

■ 26. Section 422.258 is amended in paragraphs (d)(3), (d)(5) introductory text, (d)(5)(i) introductory text, (d)(5)(ii), and (d)(6)(i) by removing the reference

''§ 422.306(c)'' and adding in its place the reference '' § 422.306(c) and (d)''.

■ 27. Section 422.306 is amended—

■ a. In the introductory text by:

■ i. Removing ''§§ 422.308(b) and 422.308(g)'' and adding in its place ''§ 422.308(b) and (g)''; and

■ ii. Removing the phrase ''year under paragraph (c) of this section'' and adding in its place the phrase ''year under paragraph (c) of this section and costs for kidney acquisitions in the area for the year under paragraph (d) of this section''; and

■ b. By adding paragraph (d).

The addition reads as follows:

§ 422.306 Annual MA capitation rates.

* * * * *

(d) *Exclusion of costs for kidney acquisitions from MA capitation rates.* Beginning with 2021, after the annual capitation rate for each MA local area is determined under paragraph (a) or (b) of this section, the amount is adjusted in accordance with section 1853(k)(5) of the Act to exclude the Secretary's estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under this title (including expenses covered under section 1881(d) of the Act) in the area for the year.

§ 422.312 [Amended]

■ 28. Section 422.312 is amended—

■ a. In paragraph (b)(1) by removing the phrase ''45 days'' and adding in its place the phrase ''60 days''; and

■ b. In paragraph (b)(2) by removing the phrase ''15 days'' and adding in its place the phrase ''30 days''.

■ 29. Section 422.322 is amended by adding paragraph (d) to read as follows:

§ 422.322 Source of payment and effect of MA plan election on payment.

* * * * *

(d) *FFS payment for expenses for kidney acquisitions.* Paragraphs (b) and (c) of this section do not apply with respect to expenses for organ acquisitions for kidney transplants described in section 1852(a)(1)(B)(i) of the Act.

■ 30. Section 422.500 is amended in paragraph (b) by adding the definitions of ''Fraud hotline tip'', ''Inappropriate prescribing'', and ''Substantiated or suspicious activities of fraud, waste, or abuse'' in alphabetical order to read as follows:

§ 422.500 Scope and definitions.

* * * * *

(b) * * *

Fraud hotline tip is a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

Inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by MA organizations and Part D plan sponsors, there is an established pattern of potential fraud, waste, and abuse related to prescribing of opioids, as reported by the plan sponsors. Plan sponsors may consider any number of factors including, but not limited to the following:

(i) Documentation of a patient's medical condition.

(ii) Identified instances of patient harm or death.

(iii) Medical records, including claims (if available).

(iv) Concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm.

(v) Levels of morphine milligram equivalent (MME) dosages prescribed.

(vi) Absent clinical indication or documentation in the care management plan or in a manner that may indicate diversion.

(vii) State-level prescription drug monitoring program (PDMP) data.

(viii) Geography, time, and distance between a prescriber and the patient.

(ix) Refill frequency and factors associated with increased risk of opioid overdose.

* * * * *

Substantiated or suspicious activities of fraud, waste, or abuse means and includes, but is not limited to, allegations that a provider of services (including a prescriber) or supplier—

(i) Engaged in a pattern of improper billing;

(ii) Submitted improper claims with suspected knowledge of their falsity;

(iii) Submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or

(iv) Is the subject of a fraud hotline tip verified by further evidence.

■ 31. Section 422.502 is amended by adding paragraphs (b)(1)(i) and (ii) to read as follows:

§ 422.502 Evaluation and determination procedures.

* * * * *

(b) * * *

(1) * * *

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) if during the applicable review period the applicant does any of the following:

(A) Was subject to the imposition of an intermediate sanction or civil money penalty under subpart O of this part, with the exception of a sanction imposed under § 422.752(d).

(B) Failed to maintain a Part C summary rating score of at least three stars consistent with § 422.504(b)(17).

(C) Failed to maintain a fiscally sound operation consistent with the requirements of § 422.504(b)(14).

(ii) CMS may deny an application submitted by an organization that does not hold a Part C contract at the time of the submission when the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (b)(1)(i) of this section.

* * * * *

■ 32. Section 422.503 is amended by adding paragraphs (b)(4)(vi)(G)(*4*) through (*7*) and (b)(5)(i) and (ii) to read as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(G) * * *

(*4*) The MA organization must have procedures to identify, and must report to CMS or its designee either of the following, in the manner described in paragraphs (b)(4)(vi)(G)(*4*) through (*6*) of this section:

(*i*) Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o)(1) of the Act.

(*ii*) Any information related to the inappropriate prescribing of opioids and concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan.

(*5*) The MA organization must submit the data elements specified in paragraphs (b)(4)(G)(vi)(*5*)(*i*) through (*lxviii*) of this section in the program integrity portal when reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies; information related to the inappropriate prescribing of opioids and concerning investigations and credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the MA organization; or if the plan reports a referral, through the portal, of substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier

related to fraud, waste, or abuse to initiate or assist with investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners. The data elements, as applicable, are as follows:

(*i*) Date of Referral.

(*ii*) Part C or Part D Issue.

(*iii*) Complainant Name.

(*iv*) Complainant Phone.

(*v*) Complainant Fax.

(*vi*) Complainant Email.

(*vii*) Complainant Organization Name.

(*viii*) Complainant Address.

(*ix*) Complainant City.

(*x*) Complainant State.

(*xi*) Complainant Zip.

(*xii*) Plan Name/Contract Number.

(*xiii*) Plan Tracking Number.

(*xiv*) Parent Organization.

(*xv*) Pharmacy Benefit Manager.

(*xvi*) Beneficiary Name.

(*xvii*) Beneficiary Phone.

(*xviii*) Beneficiary Health Insurance Claim Number (HICN).

(*xix*) Beneficiary Medicare Beneficiary Identifier (MBI).

(*xx*) Beneficiary Address.

(*xxi*) Beneficiary City.

(*xxii*) Beneficiary State.

(*xxiii*) Beneficiary Zip.

(*xxiv*) Beneficiary Date of Birth (DOB).

(*xxv*) Beneficiary Primary language.

(*xxvi*) Beneficiary requires Special Accommodations. If Yes, Describe.

(*xxvii*) Beneficiary Medicare Plan Name.

(*xxviii*) Beneficiary Member ID Number.

(*xxix*) Whether the Beneficiary is a Subject.

(*xxx*) Did the complainant contact the beneficiary. If Yes, is there a Report of the Contact?

(*xxxi*) Subject Name.

(*xxxii*) Subject Tax Identification Number (TIN).

(*xxxiii*) Does the Subject have Multiple TIN's. If Yes, provide.

(*xxxiv*) Subject NPI.

(*xxxv*) Subject DEA Number.

(*xxxvi*) Subject Medicare Provider Number.

(*xxxvii*) Subject Business.

(*xxxviii*) Subject Phone Number.

(*xxxix*) Subject Address.

(*xl*) Subject City.

(*xli*) Subject State.

(*xlii*) Subject Zip.

(*xliii*) Subject Business or Specialty Description.

(*xliv*) Secondary Subject Name.

(*xlv*) Secondary Subject Tax Identification Number (TIN)

(*xlvi*) Does the Secondary Subject have Multiple TIN's. If Yes, provide.

(*xlvii*) Secondary Subject NPI.

(*xlviii*) Secondary Subject DEA Number.

(*xlix*) Secondary Subject Medicare Provider Number.

(*l*) Secondary Subject Business.

(*li*) Secondary Subject Phone Number.

(*lii*) Secondary Subject Address.

(*liii*) Secondary Subject City.

(*liv*) Secondary Subject State.

(*lv*) Secondary Subject Zip.

(*lvi*) Secondary Subject Business or Specialty Description.

(*lvii*) Complaint Prior MEDIC Case Number.

(*lviii*) Period of Review.

(*lix*) Complaint Potential Medicare Exposure.

(*lx*) Whether Medical Records are Available.

(*lxi*) Whether Medical Records were Reviewed.

(*lxii*) Whether the submission has been Referred to Law Enforcement. Submission Accepted? If so, provide Date Accepted.

(*lxiii*) What Law Enforcement Agency(ies) has it been Referred to.

(*lxiv*) Whether HPMS Analytics and Investigations Collaboration Environment for Fraud, Waste, and Abuse (AICE–FWA) was Used.

(*lxv*) Whether the submission has indicated Patient Harm or Potential Patient Harm.

(*lxvi*) Whether the submission has been Referred. If so, provide Date Accepted.

(*lxvii*) What Agency was it Referred to.

(*lxviii*) Description of Allegations/Plan Sponsor Findings.

(*6*)(*i*) The MA organization is required to notify the Secretary, or its designee, of a payment suspension described in paragraph (b)(4)(vi)(G)(*4*)(*i*) of this section 14 days prior to implementation of the payment suspension.

(*ii*) The MA organization is required to submit the information described in paragraph (b)(4)(vi)(G)(*4*)(*ii*) of this section no later than January 15, April 15, July 15, and October 15 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. For the first reporting period (January 15, 2021), the reporting will reflect the data gathered and analyzed for the previous quarter in the calendar year (October 1–December 31).

(*7*)(*i*) CMS will provide MA organizations with data report(s) or links to the information described in paragraphs (b)(4)(vi)(G)(*4*)(*i*) and (*ii*) of this section no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30.

(*ii*) Include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders.

(*iii*) Are anonymized information submitted by plans without identifying the source of such information.

(*iv*) For the first quarterly report (April 15, 2021), that the report reflect the data gathered and analyzed for the previous quarter submitted by the plan sponsors on January 15, 2021.

(5) * * *

(i) Not accept, or share, a corporate parent organization owning a controlling interest in an entity that accepts new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

(ii) Not accept, or be either the parent organization owning a controlling interest of, or subsidiary of, an entity that accepts new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

* * * * *

■ 33. Section 422.504 is amended by revising paragraph (a)(15) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(15) Through the CMS complaint tracking system, to address and resolve complaints received by CMS against the MA organization.

* * * * *

■ 34. Section 422.514 is amended by—

■ a. Revising the section heading and the heading for paragraph (a).

■ b. Adding paragraphs (d) and (e).

The revisions and additions read as follows:

§ 422.514 Enrollment requirements.

(a) *Minimum enrollment rules.* * * *

(d) *Rule on dual eligible enrollment.* In any state where there is a dual eligible special needs plan or any other plan authorized by CMS to exclusively enroll individuals entitled to medical assistance under a state plan under title XIX, CMS does not enter into or renew a contract under this subpart for plan year 2022 or subsequent years for an MA plan that is not a specialized MA plan for special needs individuals as defined in § 422.2 which does either of the following:

(1) Projects enrollment in its bid submitted under § 422.254 that 80 percent or more enrollees of the plan's total enrollment are enrollees entitled to

medical assistance under a state plan under title XIX.

(2) Has actual enrollment, as determined by CMS using the January enrollment of the current year, consisting of 80 percent or more of enrollees who are entitled to medical assistance under a state plan under title XIX, unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination.

(e) *Transition process and procedures.* (1) For coverage effective January 1 of the next year, and subject to the disclosure requirements described in paragraph (e)(2) of this section, an MA organization may transition enrollees in a plan specified in paragraph (d)(2) of this section into another MA plan or plans (including into a dual eligible special needs plan for enrollees who are eligible for such a plan) offered by the MA organization, or another MA organization that shares the same parent organization as the MA organization, for which the individual is eligible in accordance with §§ 422.50 through 422.53 if the MA plan or plans receiving such enrollment—

(i) Would not meet the criteria in paragraph (d)(2) of this section, as determined in the procedures described in paragraph (e)(3) of this section, with the addition of the newly enrolled individuals (unless such plan is a Specialized MA plan for Special Needs Individuals as defined in § 422.2);

(ii) Is an MA–PD plan described at § 422.2; and

(iii) Has a combined Part C and Part D premium of $0.00 for individuals eligible for the premium subsidy for full subsidy eligible individuals described in § 423.780(a) of this chapter.

(2) An MA organization may transition individuals under paragraph (e)(1) of this section without requiring the individual to file the election form under § 422.66(a) if—

(i) The enrolled individual is eligible to enroll in the MA plan; and

(ii) The MA organization describes changes to MA–PD benefits and information about the MA–PD plan into which the individual is enrolled in the Annual Notice of Change, which must be sent consistent with §§ 422.111(a), (d), and (e) and 422.2267(e)(3).

(3) For the purpose of approving a MA organization to transition enrollment under this paragraph (e), CMS determines whether a non-SNP MA plan would meet the criteria in paragraph (d)(2) of this section by adding the cohort of individuals identified by the MA organization for enrollment in a non-SNP MA plan to the April enrollment of such plan and calculating the resulting percentage of dual eligible enrollment.

(4) In cases where an MA organization does not transition current enrollees under paragraph (e)(1) of this section, the MA organization must send, consistent with § 422.506(a)(2), a written notice to enrollees who are not transitioned.

■ 35. Section 422.530 is added to subpart K to read as follows:

§ 422.530 Plan crosswalks.

(a) *General rules*—(1) *Definition of crosswalk.* A crosswalk is the movement of enrollees from one plan benefit package (PBP) to another PBP under a contract between the MA organization and CMS. To crosswalk enrollees from one PBP to another is to change the enrollment from the first PBP to the second.

(2) *Prohibitions.* Except as described in paragraph (c) of this section, crosswalks are prohibited between different contracts or different plan types (for example, HMO to PPO).

(3) *Compliance with renewal/nonrenewal rules.* The MA organization must comply with renewal and nonrenewal rules in §§ 422.505 and 422.506 in order to complete plan crosswalks.

(4) *Eligibility.* Enrollees must be eligible for enrollment under §§ 422.50 through 422.54 in order to be moved from PBP to another PBP.

(5) *Types of MA plans.* For purposes of crosswalk policy in this section, CMS considers the following plans as different plan types:

(i) Health maintenance organizations coordinated care plans.

(ii) Provider-sponsored organizations coordinated care plans.

(iii) Regional or local preferred provider organizations coordinated care plans.

(iv) Special needs plans.

(v) Private Fee-for-service plans.

(vi) MSA plans.

(b) *Allowable crosswalk types*—(1) *All MA plans.* All MA plans may perform a crosswalk in the following circumstances:

(i) *Renewal.* A plan in the following contract year that links to a current contract year plan and retains the entire service area from the current contract year. The following contract year plan must retain the same plan ID as the current contract year plan.

(ii) *Consolidated renewal.* A plan in the following contract year that combines 2 or more complete current contract year plans of the same plan type but not including when a current PBP is split among more than one PBP for the following contract year. The plan ID for the following contract year must be the same as one of the current contract year plan IDs.

(iii) *Renewal with a service area expansion (SAE).* A plan in the following contract year plan that links to a current contract year plan and retains all of its plan service area from the current contract year, but also adds one or more new counties. The following year contract plan must retain the same plan ID as the current contract year plan.

(iv) *Renewal with a service area reduction (SAR).* (A) A plan in the following contract year that links to a current contract year plan and only retains a portion of its plan service area. The following contract year plan must retain the same plan ID as the current contract year plan. The crosswalk is limited to the enrollees in the remaining service area.

(B) While the MA organization may not affirmatively crosswalk enrollees in the locations that will no longer be part of the service area, the MA organization may offer the affected enrollees in the reduced portion of the service area a continuation in accordance with § 422.74(b)(3)(ii), provided that there are no other MA plan options in the reduced service area.

(C) If the MA organization offers another PBP in the locations that will no longer be part of the service area, current enrollees in the locations that will no longer be part of the service area must be disenrolled and the MA organization must send a non-renewal notice that includes notification of a special enrollment period under § 422.62 and, for applicable enrollees, Medigap guaranteed issue rights.

(D) The MA organization may offer current enrollees in the locations that will no longer be part of the service area the option of enrolling in the other plan(s) the MA organization offers in the location that is no longer part of the service area, however, no specific plan information for the following contract year may be shared with any beneficiaries prior to the plan marketing period for the next contract year.

(2) *Special needs plans (SNPs).* In addition to those described in paragraph (b)(1) of this section, SNPs may also perform the following types of crosswalks:

(i) *Chronic SNPs (C–SNPs).* (A) Renewing C–SNP with one chronic condition that transitions eligible enrollees into another C–SNP with a grouping that contains that same chronic condition.

(B) Non-renewing C–SNP with one chronic condition that transitions eligible enrollees into another C–SNP

with a grouping that contains that same chronic condition.

(C) Renewing C–SNP with a grouping that is transitioning eligible enrollees into another C–SNP with one of the chronic conditions from that grouping.

(D) Non-renewing C–SNP in a grouping that is transitioning eligible enrollees into a different grouping C–SNP if the new grouping contains at least one condition that the prior plan contained.

(ii) *Institutional SNP.* (A) Renewing Institutional SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

(B) Renewing Institutional Equivalent SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

(C) Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional SNP.

(D) Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional Equivalent SNP.

(E) Non-renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to another Institutional/Institutional Equivalent SNP.

(c) *Exceptions.* In order to perform a crosswalk that is not specified in paragraph (b) of this section, an MA organization must request an exception. Crosswalk exceptions are prohibited between different plan types. CMS reviews exception requests and permits a crosswalk exception in the following circumstances:

(1) When a non-network or partial network Private Fee-For-Service (PFFS) changes to either a partial network or to a full network PFFS plan, enrollees may be moved to the new plan when CMS determines it is in the interest of beneficiaries.

(2) When MA plans offered by two different MA organizations that share the same parent organization are consolidated such that the MA plans under separate contracts are consolidated under one surviving contract, the enrollees from the consolidating plans may be crosswalked to an MA plan under the surviving plan.

(3) When a renewing D–SNP in a multi-state service area reduces its service area to accommodate state contracting efforts in the service area, enrollees who are no longer in the service area may be moved into one or more new or renewing D–SNPs in their service area as CMS determines is necessary to accommodate changes to D–SNP state contracts.

(4) When a renewing D–SNP has another new or renewing D–SNP, and the two D–SNPs are offered to different populations, enrollees who are no longer eligible for their current D–SNP may be moved into the other new or renewing D–SNP if they meet the eligibility criteria for the new or renewing D–SNP and CMS determines it is in the best interests of the enrollees to move to the new or renewing D–SNP.

(5) Renewing C–SNP with a grouping that is transitioning eligible enrollees into another C–SNP with one of the chronic conditions from that grouping.

(d) *Procedures.* (1) An MA organization must submit all crosswalks in paragraph (b) of this section in writing through the bid submission process in HPMS by the bid submission deadline announced by CMS.

(2) An organization must submit all crosswalk exception requests in paragraph (c)(1) of this section in writing through the crosswalk exceptions process in HPMS by the crosswalk exception request deadline announced by CMS annually. CMS verifies the requests and notifies requesting organizations of the approval or denial after the crosswalk exception request deadline.

■ 36. Section 422.550 is amended by adding paragraph (f) to read as follows:

§ 422.550 General provisions.

* * * * *

(f) *Sale of beneficiaries not permitted.* (1) CMS only recognizes the sale or transfer of an organization's entire MA line of business, consisting of all MA contracts held by the MA organization with the exception of the sale or transfer of a full contract between wholly owned subsidiaries of the same parent organization, which is permitted.

(2) CMS does not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries, groups of beneficiaries enrolled in a plan benefit package, or one contract if the organization holds more than one MA contract.

■ 37. Section 422.562 is amended by adding paragraph (d)(3) to read as follows:

§ 422.562 General provisions.

* * * * *

(d) * * *

(3) For the sole purpose of applying the regulations at § 405.1038(c) of this chapter, an MA organization is included in the definition of ''contractors'' as it relates to stipulated decisions.

■ 38. Section 422.568 is amended by adding paragraphs (g) through (k) to read as follows:

§ 422.568 Standard timeframes and notice requirements for organization determinations.

* * * * *

(g) *Dismissing a request.* The MA organization may dismiss an organization determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The individual or entity making the request is not permitted to request an organization determination under § 422.566(c).

(2) The MA organization determines the party failed to make out a valid request for an organization determination that substantially complies with paragraph (a) of this section.

(3) An enrollee or the enrollee's representative files a request for an organization determination, but the enrollee dies while the request is pending, and both of the following apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the organization determination.

(4) A party filing the organization determination request submits a timely written request for withdrawal of their request for an organization determination with the MA organization.

(h) *Notice of dismissal.* The MA organization must mail or otherwise transmit a written notice of the dismissal of the organization determination request to the parties. The notice must state the all of the following:

(1) The reason for the dismissal.

(2) The right to request that the MA organization vacate the dismissal action.

(3) The right to request reconsideration of the dismissal.

(i) *Vacating a dismissal.* If good cause is established, the MA organization may vacate its dismissal of a request for an organization determination within 6 months from the date of the notice of dismissal.

(j) *Effect of dismissal.* The dismissal of a request for an organization determination is binding unless it is modified or reversed by the MA organization upon reconsideration or vacated under paragraph (i) of this section.

(k) *Withdrawing a request.* A party that requests an organization determination may withdraw its request at any time before the decision is issued by filing a written request with the MA organization.

■ 39. Section 422.570 is amended by adding paragraph (g) to read as follows:

§ 422.570 Expediting certain organization determinations.

* * * * *

(g) *Dismissing a request.* The MA organization may dismiss an expedited organization request in accordance with § 422.568.

■ 40. Section 422.582 is amended by adding paragraphs (f) through (i) to read as follows:

§ 422.582 Request for a standard reconsideration.

* * * * *

(f) *Dismissing a request.* The MA organization may dismiss a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting a reconsideration is not a proper party under § 422.578.

(2) The MA organization determines the party failed to make a valid request for a reconsideration that substantially complies with paragraph (a) of this section.

(3) The party fails to file the reconsideration request within the proper filing time frame in accordance with paragraph (b) of this section.

(4) The enrollee or the enrollee's representative files a request for a reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the reconsideration.

(5) A party filing the reconsideration request submits a timely written request for withdrawal of the request for a reconsideration with the MA organization.

(g) *Notice of dismissal.* The MA organization must mail or otherwise transmit a written notice of the dismissal of the reconsideration request to the parties. The notice must state the all of the following:

(1) The reason for the dismissal.

(2) The right to request that the MA organization vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(h) *Vacating a dismissal.* If good cause is established, the MA organization may vacate its dismissal of a request for reconsideration within 6 months from the date of the notice of dismissal.

(i) *Effect of dismissal.* The MA organization's dismissal is binding unless the enrollee or other party requests review by the independent entity in accordance with § 422.590(h) or the decision is vacated under paragraph (h) of this section.

■ 41. Section 422.584 is amended by adding paragraph (g) to read as follows:

§ 422.584 Expediting certain reconsiderations.

* * * * *

(g) *Dismissing a request.* The MA organization may dismiss an expedited reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting an expedited reconsideration is not a proper party under paragraph (a) of this section.

(2) When the MA organization determines the party failed to make a valid request for an expedited reconsideration that substantially complies with paragraph (b) of this section.

(3) When the party fails to file the expedited reconsideration request within the proper filing time frame in accordance with § 422.572(a).

(4) When the enrollee or the enrollee's representative files a request for an expedited reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the expedited reconsideration.

(5) When a party filing the expedited reconsideration request submits a timely written request for withdrawal of their request for an expedited reconsideration with the MA organization.

■ 42. Section 422.590 is amended by adding paragraph (i) to read as follows:

§ 422.590 Timeframes and responsibility for reconsiderations.

* * * * *

(i) *Requests for review of a dismissal by the independent entity.* If the MA organization dismisses a request for a reconsideration in accordance with §§ 422.582(f) and 422.584(g), the enrollee or other party has the right to request review of the dismissal by the independent entity. A request for review of a dismissal must be filed in writing with the independent entity within 60 calendar days from the date of the MA organization's dismissal notice.

■ 43. Section 422.592 is amended by revising paragraph (a) and adding paragraphs (d) through (i) to read as follows:

§ 422.592 Reconsideration by an independent entity.

(a) When the MA organization affirms, in whole or in part, its adverse organization determination, the issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with CMS. In accordance with § 422.590(h), the independent entity is responsible for reviewing MA organization dismissals of reconsideration requests.

* * * * *

(d) The independent entity may dismiss a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting a reconsideration is not a proper party under § 422.578(c).

(2) The independent entity determines the party failed to make out a valid request for a reconsideration that substantially complies with § 422.582(a) or (b).

(3) The enrollee or the enrollee's representative files a request for a reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the reconsideration.

(4) The party filing the reconsideration request submits with the independent review entity a timely written request for withdrawal of the request for reconsideration.

(e) The independent entity mails or otherwise transmits a written notice of the dismissal of the reconsideration request to the parties. The notice must state the following:

(1) The reason for the dismissal.

(2) That there is a right to request that the independent entity vacate the dismissal action.

(3) The right to a review of the dismissal under §§ 422.600 and 422.602.

(f) If good cause is established, the independent entity may vacate its dismissal of a request for reconsideration within 6 months from the date of the notice of dismissal.

(g) The independent entity's dismissal is binding and not subject to further review unless a party meets the requirements in § 422.600 and files a proper and timely request under § 422.602 or the dismissal is vacated under paragraph (f) of this section.

(h) The party or physician acting on behalf of an enrollee who files a request for reconsideration may withdraw the request by filing a written request for

withdrawal with the independent entity.

(i) If the independent entity determines that the MA organization's dismissal was in error, the independent entity vacates the dismissal and remands the case to the plan for reconsideration. The independent entity's decision regarding an MA organization's dismissal, including a decision to deny a request for review of a dismissal, is binding and not subject to further review.

■ 44. Section 422.600 is amended by revising paragraph (b) to read as follows:

§ 422.600 Right to a hearing.

* * * * *

(b) The amount remaining in controversy, which can include any combination of Part A and Part B services, is computed in accordance with part 405 of this chapter. For purposes of calculating the amount remaining in controversy under this section, references to coinsurance in § 405.1006(d) of this chapter should be read to include coinsurance and copayment amounts.

* * * * *

■ 45. Section 422.629, as added on April 16, 2019 (84 FR 15835) effective January 1, 2021, is amended by revising paragraph (k)(4)(ii) to read as follows:

§ 422.629 General requirements for applicable integrated plans.

* * * * *

(k) * * *

(4) * * *

(ii) If deciding an appeal of a denial that is based on lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), are a physician or other appropriate health care professional who have the appropriate clinical expertise in treating the enrollee's condition or disease, and knowledge of Medicare and Medicaid coverage criteria, before the applicable integrated plan issues the integrated organization determination decision.

* * * * *

■ 46. Section 422.631, as added on April 16, 2019 (84 FR 15835) effective January 1, 2021, is amended by adding paragraphs (e) through (i) to read as follows:

§ 422.631 Integrated organization determinations.

* * * * *

(e) *Dismissing a request.* The applicable integrated plan may dismiss a standard or expedited integrated organization determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The individual or entity making the request is not permitted to request an integrated organization determination under § 422.629(l).

(2) The applicable integrated plan determines the party failed to make out a valid request for an integrated organization determination that substantially complies with paragraph (b) of this section.

(3) An enrollee or the enrollee's representative files a request for an integrated organization determination, but the enrollee dies while the request is pending, and both of the following apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the integrated organization determination.

(4) A party filing the integrated organization determination request submits a timely written request for withdrawal of their request for an integrated organization determination with the applicable integrated plan.

(f) *Notice of dismissal.* The applicable integrated plan must mail or otherwise transmit a written notice of the dismissal of the integrated organization determination request to the parties. The notice states that there is a right to request that the applicable integrated plan vacate the dismissal action.

(g) *Vacating a dismissal.* If good cause is established, the applicable integrated plan may vacate its dismissal of a request for an integrated organization determination within 6 months from the date of the notice of dismissal.

(h) *Effect of dismissal.* The dismissal of a request for an integrated organization determination is binding unless it is modified or reversed by the applicable integrated plan or vacated under paragraph (g) of this section.

(i) *Withdrawing a request.* A party that requests an integrated organization determination may withdraw its request at any time before the decision is issued by filing a written request with the applicable integrated plan.

§ 422.632 [Amended]

■ 47. Section 422.632, as added on April 16, 2019 (84 FR 15835) effective January 1, 2021, is amended in paragraph (b)(1) by removing the reference ''§ 422.633(e)'' and adding in its place the reference ''§ 422.633(d)''.

■ 48. Section 422.633, as added on April 16, 2019 (84 FR 15835) effective January 1, 2021, is amended by adding paragraphs (g) through (k) to read as follows:

§ 422.633 Integrated reconsideration.

* * * * *

(g) *Withdrawing a request.* The party or physician acting on behalf of an enrollee who files a request for integrated reconsideration may withdraw it by filing a written request for withdrawal with the applicable integrated plan.

(h) *Dismissing a request.* The applicable integrated plan may dismiss an expedited or standard integrated reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting an integrated reconsideration is not a proper party to request an integrated reconsideration under § 422.629(l).

(2) The applicable integrated plan determines the party failed to make a valid request for an integrated reconsideration that substantially complies with § 422.629(l) of this section.

(3) The party fails to file the integrated reconsideration request within the proper filing timeframe in accordance with paragraph (d) of this section.

(4) The enrollee or the enrollee's representative files a request for an integrated reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the integrated reconsideration.

(5) A party filing the reconsideration request submits a timely written request for withdrawal of their request for an integrated reconsideration with the applicable integrated plan.

(i) *Notice of dismissal.* The applicable integrated plan must mail or otherwise transmit a written notice of the dismissal of the integrated reconsideration request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the applicable integrated plan vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(j) *Vacating a dismissal.* If good cause is established, the applicable integrated plan may vacate its dismissal of a request for integrated reconsideration within 6 months from the date of the notice of dismissal.

(k) *Effect of dismissal.* The applicable integrated plan's dismissal is binding unless the enrollee or other party requests review by the independent entity in accordance with § 422.590(h).

■ 49. Section 422.760 is amended by redesignating paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5), respectively, and adding a new paragraph (b)(3) to read as follows:

§ 422.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

* * * * *

(b) * * *

(3) CMS calculates the minimum penalty amounts under paragraphs (b)(1) and (2) of this section using the following criteria:

(i) *Definitions for calculating penalty amounts*—(A) *Per determination.* The penalty amounts calculated under paragraph (b)(1) of this section.

(B) *Per enrollee.* The penalty amounts calculated under paragraph (b)(2) of this section.

(C) *Standard minimum penalty.* The per enrollee or per determination penalty amount that is dependent on the type of adverse impact that occurred.

(D) *Aggravating factor(s).* Specific penalty amounts that may increase the per enrollee or per determination standard minimum penalty and are determined based on criteria under paragraph (a) of this section.

(E) *Cost-of-living multiplier.* The percent change between each year's published October consumer price index for all urban consumers (United States city average), which is released by The Office of Management and Budget (OMB) annually.

(ii) *Calculation of minimum penalty amounts.* (A) Per determination and per enrollee minimum penalty amounts increases by multiplying the current standard minimum penalty and aggravating factor amounts by the cost-of-living multiplier.

(B) The minimum penalty and aggravating factor amounts is updated no more often than every 3 years.

(C) CMS does the following:

(*1*) Tracks the calculation and accrual of the standard minimum penalty and aggravating factor amounts.

(*2*) Announces the penalties and amounts described in paragraph (b) of this section on an annual basis.

* * * * *

■ 50. Section 422.2260 is revised to read as follows:

§ 422.2260 Definitions.

The definitions in this section apply for this subpart unless the context indicates otherwise.

Advertisement (Ad) means a read, written, visual, oral, watched, or heard bid for call to attention. Advertisements can be considered communications or marketing based on the intent and content of the message.

Alternate format means a format used to convey information to individuals with visual, speech, physical, hearing, and intellectual disabilities (for example, braille, large print, audio).

Banner means a type of advertisement feature typically used in television ads that is intended to be brief, and flashes limited information across a screen for the sole purpose of enticing a prospective enrollee to contact the MA plan (for example, obtain more information) or to alert the viewer that information is forthcoming.

Banner-like advertisement is an advertisement that uses a banner-like feature, that is typically found in some media other than television (for example, outdoors and on the internet).

Communications means activities and use of materials created or administered by the MA organization or any downstream entity to provide information to current and prospective enrollees. Marketing is a subset of communications.

Marketing means communications materials and activities that meet both the following standards for intent and content:

(1) Intended, as determined under paragraph (1)(ii) of this definition, to do any of the following:

(i)(A) Draw a beneficiary's attention to a MA plan or plans.

(B) Influence a beneficiary's decision-making process when making a MA plan selection.

(C) Influence a beneficiary's decision to stay enrolled in a plan (that is, retention-based marketing).

(ii) In evaluating the intent of an activity or material, CMS will consider objective information including, but not limited to, the audience of the activity or material, other information communicated by the activity or material, and timing and other context of the activity or material and is not limited to the MA organization's stated intent.

(2) Include or address content regarding any of the following:

(i) The plan's benefits, benefits structure, premiums, or cost sharing.

(ii) Measuring or ranking standards (for example, star ratings or plan comparisons).

(iii) Rewards and incentives as defined under § 422.134(a).

Outdoor advertising (ODA) means outdoor material intended to capture the attention of a passing audience (for example, billboards, signs attached to transportation vehicles). ODA may be communications or marketing material.

■ 51. Section 422.2261 is added to read as follows:

§ 422.2261 Submission, review, and distribution of materials.

(a) *General requirements.* MA organizations must submit all marketing materials, all election forms, and certain designated communications materials for CMS review.

(1) The Health Plan Management System (HPMS) Marketing Module is the primary system of record for the collection, review, and storage of materials that must be submitted for review.

(2) Materials must be submitted to the HPMS directly by the MA organization. Third party and downstream entities are not permitted to submit materials directly to CMS.

(b) *CMS review of marketing materials and election forms.* MA organizations may not distribute or otherwise make available any marketing materials (as defined in § 422.2260) or election forms unless one of the following occurs:

(1) CMS has reviewed and approved the material.

(2) The material has been deemed approved; that is, CMS has not rendered a disposition for the material within 45 days (or 10 days if using CMS model or standardized marketing materials as outlined in § 422.2267(e)) of submission to CMS; or

(3) The material has been accepted under File and Use, as follows:

(i) The MA organization may distribute certain types of marketing materials, designated by CMS based on the material's content, audience, and intended use, as they apply to potential risk to the beneficiary, 5 days following the submission.

(ii) The MA organization must certify that the material meets all applicable CMS communications and marketing requirements in §§ 422.2260 through 422.2267.

(c) *CMS review of communications materials.* CMS does not generally require submission and approval of communications materials prior to use, with the exception of certain designated communications materials that are critical to the beneficiary understanding or accessing their benefits (for example, the Evidence of Coverage (EOC)).

(d) *Standards for CMS review.* CMS reviews materials to ensure the following:

(1) Compliance with all applicable requirements under §§ 422.2260 through 422.2267.

(2) Benefit and cost information is an accurate reflection of what is contained in the MA organization's bid.

■ 52. Section 422.2262 is revised to read as follows:

§ 422.2262 General communications materials and activities requirements.

MA organizations may not mislead, confuse, or provide inaccurate information to current or potential enrollees.

(a) *General rules.* MA organizations must ensure their statements and the terminology used in communications activities and materials adhere to the following requirements:

(1) MA organizations may not do any of the following:

(i) Provide information that is inaccurate or misleading.

(ii) Make unsubstantiated statements, including superlatives or pejoratives.

(iii) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the MA organization.

(iv) Engage in any discriminatory activity such as attempting to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas, or vice versa.

(v) Target potential enrollees based on income levels, unless it is a dual eligible special needs plan or comparable plan as determined by the Secretary.

(vi) Target potential enrollees based on health status, unless it is a special needs plan or comparable plan as determined by the Secretary.

(vii) State or imply plans are only available to seniors rather than to all Medicare beneficiaries.

(viii) Employ MA plan names that suggest that a plan is not available to all Medicare beneficiaries, unless it is a special needs plan or comparable plan as determined by the Secretary. This prohibition does not apply to MA plan names in effect prior to July 31, 2000.

(ix) Display the names or logos or both of co-branded network providers on the organization's member identification card, unless the provider names or logos or both are related to the member selection of specific provider organizations (for example, physicians or hospitals).

(x) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name, for example, ''Super Medicare Advantage (HMO).''

(xi) Claim they are recommended or endorsed by CMS, Medicare, or the HHS.

(xii) Convey that a failure to pay premium will not result in disenrollment.

(xiii) Use the term ''free'' to describe a $0 premium, any type of reduction in premium, reduction in deductibles or cost sharing, low-income subsidy, or cost sharing for dual eligible individuals.

(xiv) Imply that the plan operates as a supplement to Medicare.

(xv) State or imply a plan is available only to or is designed for beneficiaries who are dually eligible for Medicare and Medicaid, unless it is a dual-eligible special needs plan or comparable plan as determined by the Secretary.

(xvi) Market a non-dual eligible special needs plan as if it were a dual-eligible special needs plan.

(xvii) Target marketing efforts primarily to dual eligible individuals, unless the plan is a dual eligible special needs plan or comparable plan as determined by the Secretary.

(xviii) Claim a relationship with the state Medicaid agency, unless a contract to coordinate Medicaid services for that plan is in place.

(2) MA organizations may do the following:

(i) State that the MA organization is approved to participate in Medicare programs or is contracted to administer Medicare benefits or both.

(ii) Use the term ''Medicare-approved'' to describe benefits or services in materials or both.

(iii) Use the term ''free'' in conjunction with mandatory, supplemental, and preventative benefits provided at a zero cost share for all enrollees.

(b) *Product endorsements and testimonials.* (1) Product endorsements and testimonials may take any of the following forms:

(i) Television or video ads.

(ii) Radio ads.

(iii) Print ads.

(iv) Social media ads. In cases of social media, the use of a previous post, whether or not associated with or originated by the MA organization, is considered a product endorsement or testimonial.

(v) Other types of ads.

(2) MA organizations may use individuals to endorse the MA organization's product provided the endorsement or testimonial adheres to the following requirements:

(i) The speaker must identify the MA organization's product or company by name.

(ii) Medicare beneficiaries endorsing or promoting the MA organization must have been an enrollee at the time the endorsement or testimonial was created.

(iii) The endorsement or testimonial must clearly state that the individual was paid for the endorsement or testimonial, if applicable.

(iv) If an individual is used (for example, an actor) to portray a real or fictitious situation, the endorsement or testimonial must state that it is an actor portrayal.

(c) *Requirements when including certain telephone numbers in materials.* (1) MA organizations must adhere to the following requirements for including certain telephone numbers in materials:

(i) When a MA organization includes its customer service number, the hours of operation must be included the first time (at a minimum) the number appears.

(ii) When a MA organization includes its customer service number, it must provide a toll-free TTY number in conjunction with the customer service number in the same font size.

(iii) On every material where 1–800–MEDICARE or Medicare TTY appears, the MA organization must include the hours and days of operation for 1–800–MEDICARE (that is, 24 hours a day/7 days a week).

(2) The following advertisement types are exempt from these requirements:

(i) Outdoor advertising.

(ii) Banners or banner-like ads.

(iii) Radio advertisements and sponsorships.

(d) *Standardized material identification (SMID).* (1) MA organizations must use a standardized method of identification for oversight and tracking of materials beneficiaries receive.

(2) The SMID consists of the following three parts:

(i) The MA organization contract or Multi-Contract Entity (MCE) number (that is, ''H'' for MA or Section 1876 Cost Plans, ''R'' for Regional PPO plans (RPPOs), or ''Y'' for MCE identifier) followed by an underscore, except that the SMID for multi-plan marketing materials must begin with the word ''MULTI–PLAN'' instead of the MA organization's contract number (for example, H1234_abc123_C or MULTI–PLAN_efg456_M).

(ii) A series of alpha numeric characters (chosen at the MA organization's discretion) unique to the material followed by an underscore.

(iii) An uppercase ''C'' for communications materials or an uppercase ''M'' for marketing materials (for example, H1234_abc123_C or H5678_efg456_M).

(3) The SMID is required on all materials except the following:

(i) Membership ID card.

(ii) Envelopes, radio ads, outdoor advertisements, banners, banner-like

ads, and social media comments and posts.

(iii) OMB-approved forms/documents, except those materials included in § 422.2267.

(iv) Corporate notices or forms (that is, not MA/Part D specific) meeting the definition of communications (see § 422.2260) such as privacy notices and authorization to disclose protected health information (PHI).

(v) Agent-developed communications materials that are not marketing.

(4) Non-English and alternate format materials, based on previously created materials, may have the same SMID as the material on which they are based.

■ 53. Section 422.2263 is added to read as follows:

§ 422.2263 General marketing requirements.

Marketing is a subset of communications and therefore must follow the requirements outlined in § 422.2262 as well as this section. Marketing (as defined in § 422.2260) must additionally meet the following requirements:

(a) MA organizations may begin marketing prospective plan year offerings on October 1 of each year for the following contract year. MA organizations may market the current and prospective year simultaneously provided materials clearly indicate what year is being discussed.

(b) In marketing, MA organizations may not do any of the following:

(1) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.

(2) Offer gifts to potential enrollees, unless the gifts are of nominal value (as governed by guidance published by the HHS OIG), are offered to all potential enrollees without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

(3) Provide meals to potential enrollees regardless of value.

(4) Market non-health care related products to prospective enrollees during any MA sales activity or presentation. This is considered cross-selling and is prohibited.

(5) Compare their plan to other plans, unless the information is accurate, not misleading, and can be supported by the MA organization making the comparison.

(6) Display the names or logos or both of provider co-branding partners on marketing materials, unless the materials clearly indicate via a disclaimer or in the body that ''Other providers are available in the network.''

(7) Knowingly target or send unsolicited marketing materials to any MA enrollee during the Open Enrollment Period (OEP).

(i) During the OEP, an MA organization may do any of the following:

(A) Conduct marketing activities that focus on other enrollment opportunities, including but not limited to marketing to age-ins (who have not yet made an enrollment decision), marketing by 5-star plans regarding their continuous enrollment SEP, and marketing to dual-eligible and LIS beneficiaries who, in general, may make changes once per calendar quarter during the first 9 months of the year;

(B) Send marketing materials when a beneficiary makes a proactive request;

(C) At the beneficiary's request, have one-on-one meetings with a sales agent; and

(D) At the beneficiary's request, provide information on the OEP through the call center.

(ii) During the OEP, an MA organization may not:

(A) Send unsolicited materials advertising the ability/opportunity to make an additional enrollment change or referencing the OEP;

(B) Specifically target beneficiaries who are in the OEP because they made a choice during Annual Enrollment Period (AEP) by purchase of mailing lists or other means of identification;

(C) Engage in or promote agent/broker activities that intend to target the OEP as an opportunity to make further sales; or

(D) Call or otherwise contact former enrollees who have selected a new plan during the AEP.

(c) The following requirements apply to how MA organizations must display CMS issued Star Ratings:

(1) References to individual Star Rating measure(s) must also include references to the overall Star Rating.

(2) May not use an individual underlying category or measure to imply overall high Star Ratings.

(3) Must be clear that the rating is out of 5 stars.

(4) Must clearly identify the Star Rating contract year.

(5) May only market the Star Ratings in the service area in which the Star Rating is applicable.

(6) The following requirements apply to all 5 Star MA contracts:

(i) May not market the 5 star special enrollment period, as defined in § 422.62(b)(15), after November 30 of each year if the contract has not received an overall 5 star for the next contract year.

(ii) May use CMS' 5 star icon or may create their own icon.

(7) The following requirements apply to all Low Performing MA contracts:

(i) The Low Performing Icon must be included on all materials about or referencing the specific contract's Star Ratings.

(ii) Must state the Low Performing Icon means that the MA organization's contract received a summary rating of 2.5 stars or below in Part C or Part D or both for the last 3 years.

(iii) May not attempt to refute or minimize Low Performing Status.

■ 54. Section 422.2264 is revised to read as follows:

§ 422.2264 Beneficiary contact.

For the purpose of this section, beneficiary contact applies to all outreach activities to a beneficiary or a beneficiary's caregivers by the MA organization or its agents and brokers.

(a) *Unsolicited contact.* Subject to the rules for contact for plan business in paragraph (b) of this section, the following rules apply when materials or activities are given or supplied to a beneficiary or their caregiver without prior request:

(1) MA organizations may make unsolicited direct contact by conventional mail and other print media (for example, advertisements and direct mail) or email (provided every email contains an opt-out option).

(2) MA organizations may not do any of the following:

(i) Use door to door solicitation, including leaving information of any kind, except that information may be left when an appointment is pre-scheduled but the beneficiary is not home.

(ii) Approach enrollees in common areas such as parking lots, hallways, and lobbies.

(iii) Unsolicited direct messages from social media platforms.

(iv) Use telephone solicitation (that is, cold calling), text messages, or voicemail messages, including, but not limited to, the following:

(A) Unsolicited calls based on referrals.

(B) Calls to former enrollees who have disenrolled or those in the process of disenrolling, except to conduct disenrollment surveys for quality improvement purposes.

(C) Calls to beneficiaries who attended a sales event, unless the beneficiary gave express permission to be contacted.

(D) Unsolicited calls to prospective enrollees to confirm receipt of mailed information.

(3) Calls are not considered unsolicited if the beneficiary provides consent or initiates contact with the plan. For example, returning phone calls or calling an individual who has

completed a business reply card requesting contact is not considered unsolicited.

(4) MA organizations are responsible for ensuring sales staff, including agents and brokers, abide by Federal and state laws related to consumer protection, including, but not limited to, do not call requirements.

(b) *Contact for plan business.* MA organizations may contact current, and to a more limited extent, former members, including those enrolled in other products offered by the parent organization, to discuss plan business, in accordance with the following requirements:

(1) An MA organization may conduct the following activities as plan business:

(i) Call current enrollees, including those in non-Medicare products, to discuss Medicare products. Examples of such calls include, but are not limited to the following:

(A) Enrollees aging into Medicare from commercial products.

(B) Existing enrollees, including Medicaid enrollees, to discuss other Medicare products or plan benefits.

(C) Members in a Part D plan to discuss other Medicare products.

(ii) Call beneficiaries who submit enrollment applications to conduct business related to enrollment.

(iii) With prior CMS approval, call LIS enrollees that a plan is prospectively losing to due reassignment. CMS decisions to approve calls are for limited circumstances based on the following:

(A) The proximity of cost of the losing plan as compared to the national benchmark; and

(B) The selection of plans in the service area that are below the benchmark.

(iv) Agents/brokers calling clients who are enrolled in other products they may sell, such as automotive or home insurance.

(v) MA organizations may not make unsolicited calls about other lines of business as a means of generating leads for Medicare plans.

(2) [Reserved]

(c) *Events with beneficiaries.* MA organizations and their agent/brokers may hold educational events, marketing or sales events, and personal marketing appointments to meet with Medicare beneficiaries, either face-to-face or virtually. The requirements for each type of event are as follows:

(1) Educational events must be advertised as such and be designed to generally inform beneficiaries about Medicare, including Medicare Advantage, Prescription Drug programs, or any other Medicare program.

(i) At educational events, MA organizations and agents/brokers may not market specific MA plans or benefits.

(ii) MA organizations holding or participating in educational events may do any of the following:

(A) Distribute communications materials.

(B) Answer beneficiary-initiated questions pertaining to MA plans.

(C) Set up future personal marketing appointments.

(D) Distribute business cards.

(E) Obtain beneficiary contact information, including Scope of Appointment forms.

(iii) MA organizations holding or participating in educational events may not conduct sales or marketing presentations or distribute or accept plan applications.

(2) Marketing or sales events are group events that fall within the definition of marketing at § 422.2260.

(i) If a marketing event directly follows an educational event, the MA organization or agent/broker must provide an opportunity for beneficiaries to determine if they want to continue onto the marketing event.

(ii) MA organizations holding or participating in marketing events may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Collect Scope of Appointment forms for future personal marketing appointments.

(D) Conduct marketing presentations.

(iii) MA organizations holding or participating in marketing events may not do any of the following:

(A) Require sign-in sheets or require attendees to provide contact information as a prerequisite for attending an event.

(B) Conduct activities, including health screenings, health surveys, or other activities that are used for or could be viewed as being used to target a subset of members (that is, ''cherry-picking'').

(C) Use information collected for raffles or drawings for any purpose other than raffles or drawings.

(3) Personal marketing appointments are those appointments that are tailored to an individual or small group (for example, a married couple). Personal marketing appointments are not defined by the location.

(i) Prior to the personal marketing appointment beginning, the MA plan (or agent/broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies).

(ii) MA organizations holding a personal marketing appointment may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Conduct marketing presentations.

(D) Review the individual needs of the beneficiary including, but not limited to, health care needs and history, commonly used medications, and financial concerns.

(iii) MA organizations holding a personal marketing appointment may not do any of the following:

(A) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

(B) Market additional health related lines of plan business not identified prior to an individual appointment without a separate Scope of Appointment identifying the additional lines of business to be discussed.

(C) Market non-health related products, such as annuities.

■ 55. Section 422.2265 is added to read as follows:

§ 422.2265 Websites.

As required under § 422.111(h)(2), MA organizations must have a website.

(a) *General website requirements.* (1) MA organization websites must meet the all of the following requirements:

(i) Maintain current year contract content through December 31 of each year.

(ii) Notify users when they will leave the MA organization's Medicare site.

(iii) Include or provide access to (for example, through a hyperlink) applicable disclaimers with corresponding content. Overarching disclaimers, such as the Federal Contracting Statement, are not required on every page.

(iv) Be updated to reflect the most current information within 30 days of any information on the website changing.

(v) Keep MA content separate and distinct from other lines of business, including Medicare Supplemental Plans.

(2) MA organization websites may not do any of the following:

(i) Require beneficiaries to enter any information other than zip code, county, or state for access to non-beneficiary-specific website content.

(ii) Provide links to foreign drug sales, including advertising links.

(iii) State that the MA organization is not responsible for the content of their social media pages or the website of any first tier, downstream, or related entity that provides information on behalf of the MA organization.

(b) *Required content.* MA organization's websites must include the following content:

(1) A toll-free customer service number, TTY number, and days and hours of operation.

(2) A physical or Post Office Box address.

(3) A PDF or copy of a printable provider directory.

(4) A searchable provider directory.

(5) When applicable, a searchable pharmacy directory combined with a provider directory.

(6) Information on enrollees' and MA organizations' rights and responsibilities upon disenrollment. MA organizations may either post this information or provide specific information on where it is located in the Evidence of Coverage together with a link to that document.

(7) A description of and information on how to file a grievance, organizational determination, and appeal.

(8) Prominently display a link to the *Medicare.gov* electronic complaint form.

(9) A Privacy Notice under the HIPAA Privacy Rule (45 CFR part 160).

(10) For PFFS plans, a link to the PFFS Terms and Conditions of Payment.

(11) For MSA plans, the following statements:

(i) ''You must file Form 1040, 'US Individual Income Tax Return,' along with Form 8853, 'Archer MSA and Long-Term Care Insurance Contracts' with the Internal Revenue Service (IRS) for any distributions made from your Medicare MSA account to ensure you aren't taxed on your MSA account withdrawals. You must file these tax forms for any year in which an MSA account withdrawal is made, even if you have no taxable income or other reason for filing a Form 1040. MSA account withdrawals for qualified medical expenses are tax free, while account withdrawals for non-medical expenses are subject to both income tax and a fifty (50) percent tax penalty.''

(ii) ''Tax publications are available on the IRS website at *http://www.irs.gov* or from 1–800–TAX–FORM (1–800–829–3676).''

(c) *Required posted materials.* MA organization's website must provide access to the following materials, in a printable format, within the timeframes noted in paragraphs (c)(1) and (2) of this section.

(1) The following documents for each plan year must be posted on the website by October 15 prior to the beginning of the plan year:

(i) Evidence of Coverage.

(ii) Annual Notice of Change (for renewing plans).

(iii) Summary of Benefits.

(iv) Provider Directory.

(v) Provider/Pharmacy Directory.

(2) The following documents must be posted on the website throughout the year and be updated as required:

(i) Prior Authorization Forms for physicians and enrollees.

(ii) When applicable, Part D Model Coverage Determination and Redetermination Request Forms.

(iii) Exception request forms for physicians (which must be posted by January 1 for new plans).

(iv) CMS Star Ratings document, which must be posted within 21 days after its release on the Medicare Plan Finder.

■ 56. Section 422.2266 is added to read as follows:

§ 422.2266 Activities with healthcare providers or in the healthcare setting.

(a) *Where marketing is prohibited.* The requirements in paragraphs (c) through (e) of this section apply to activities in the health care setting. Marketing activities and materials are not permitted in areas where care is being administered, including but not limited to the following:

(1) Exam rooms.

(2) Hospital patient rooms.

(3) Treatment areas where patients interact with a provider and clinical team (including dialysis treatment facilities).

(4) Pharmacy counter areas.

(b) *Where marketing is permitted.* Marketing activities and materials are permitted in common areas within the health care setting, including, are not limited to, the following:

(1) Common entryways.

(2) Vestibules.

(3) Waiting rooms.

(4) Hospital or nursing home cafeterias.

(5) Community, recreational, or conference rooms.

(c) *Provider-initiated activities.* Provider-initiated activities are activities conducted by a provider at the request of the patient, or as a matter of a course of treatment, and occur when meeting with the patient as part of the professional relationship between the provider and patient. Provider-initiated activities do not include activities conducted at the request of the MA organization or pursuant to the network participation agreement between the MA organization and the provider. Provider-initiated activities that meet the definition in this paragraph (c) fall outside of the definition of marketing in § 422.2260. Permissible provider-initiated activities include:

(1) Distributing unaltered, printed materials created by CMS, such as reports from Medicare Plan Finder, the ''Medicare & You'' handbook, or ''Medicare Options Compare'' (from *https://www.medicare.gov*), including in areas where care is delivered.

(2) Providing the names of MA organizations with which they contract or participate or both.

(3) Answering questions or discussing the merits of a MA plan or plans, including cost sharing and benefit information, including in areas where care is delivered.

(4) Referring patients to other sources of information, such as State Health Insurance Assistance Program (SHIP) representatives, plan marketing representatives, State Medicaid Office, local Social Security Offices, CMS' website at *https://www.medicare.gov,* or 1–800–MEDICARE.

(5) Referring patients to MA plan marketing materials available in common areas;

(6) Providing information and assistance in applying for the LIS.

(7) Announcing new or continuing affiliations with MA organizations, once a contractual agreement is signed. Announcements may be made through any means of distribution.

(d) *Plan-initiated provider activities.* Plan-initiated provider activities are those activities conducted by a provider at the request of an MA organization. During a plan-initiated provider activity, the provider is acting on behalf of the MA organization. For the purpose of plan-initiated activities, the MA organization is responsible for compliance with all applicable regulatory requirements.

(1) During plan-initiated provider activities, MA organizations must ensure that the provider does not:

(i) Accept or collect Scope of Appointment forms.

(ii) Accept Medicare enrollment applications.

(iii) Make phone calls or direct, urge, or attempt to persuade their patients to enroll in a specific plan based on financial or any other interests of the provider.

(iv) Mail marketing materials on behalf of the MA organization.

(v) Offer inducements to persuade patients to enroll in a particular MA plan or organization.

(vi) Conduct health screenings as a marketing activity.

(vii) Distribute marketing materials or enrollment forms in areas where care is being delivered.

(viii) Offer anything of value to induce enrollees to select the provider.

(ix) Accept compensation from the MA organization for any marketing or enrollment activities.

(2) During plan-initiated provider activities, the provider may do any of the following:

(i) Make available, distribute, and display communications materials, including in areas where care is being delivered.

(ii) Provide or make available marketing materials and enrollment forms in common areas.

(e) *MA organization activities in the health care setting.* MA organization activities in the health care setting are those activities, including marketing activities, that are conducted by MA organization staff or on behalf of the MA organization or any downstream entity, but not by a provider. All marketing must follow the requirements in paragraphs (a) and (b) of this section. However, during MA organization activities, the following is permitted:

(1) Accepting and collect Scope of Appointment forms.

(2) Accepting enrollment forms.

(3) Making available, distributing, and displaying communications materials, including in areas where care is being delivered.

■ 57. Section 422.2267 is added to read as follows:

§ 422.2267 Required materials and content.

For information CMS deems to be vital to the beneficiary, including information related to enrollment, benefits, health, and rights, the agency may develop materials or content that are either standardized or provided in a model form. Such materials and content are collectively referred to as *required.*

(a) *Standards for required materials and content.* All required materials and content, regardless of categorization as standardized in paragraph (b) of this section or model in paragraph (c) of this section, must meet the following:

(1) Be in a 12pt font, Times New Roman or equivalent.

(2) For markets with a significant non-English speaking population, be in the language of these individuals. Specifically, MA organizations must translate required materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

(3) Be provided to the beneficiary within CMS's specified timeframes.

(b) *Standardized materials.* Standardized materials and content are required materials and content that must be used in the form and manner provided by CMS.

(1) When CMS issues standardized material or content, an MA organization must use the document without alteration except for the following:

(i) Populating variable fields.

(ii) Correcting grammatical errors.

(iii) Adding customer service phone numbers.

(iv) Adding plan name, logo, or both.

(v) Deleting content that does not pertain to the plan type (for example, removing Part D language for a MA-only plan).

(vi) Adding the SMID.

(vii) Adding the Privacy Notice under the HIPAA Privacy Rule.

(2) The MA organization may develop accompanying language for standardized material or content, provided it does not conflict with the standardized material or content. For example, CMS may issue standardized content associated with an appeal notification. MA organizations may draft a letter that includes the standardized content in the body of the letter. The remaining language in the letter is at the plan's discretion, provided it does not conflict with the standardized content.

(c) *Model materials.* Model materials and content are those required materials and content created by CMS as an example of how to convey beneficiary information. When drafting required materials or content based on CMS models, MA organizations:

(1) Must accurately convey the vital information in the required material or content to the beneficiary, although the MA organization is not required to use CMS model materials or content verbatim; and

(2) Must follow CMS's specified order of content, when specified.

(d) *Delivery of required materials.* MA organizations must mail required materials in hard copy or provide them electronically, following the requirements in paragraphs (d)(1) and (2) of this section.

(1) For hard copy mailed materials, each enrollee must receive his or her own copy, except in cases of non-beneficiary-specific material(s) where the MA organization has determined multiple enrollees are living in the same household and it has reason to believe the enrollees are related. In that case, the MA organization may mail one copy to the household. The MA organization must provide all enrollees an opt-out process so the enrollees can each receive his or her own copy, instead of a copy to the household. Materials specific to an individual beneficiary must always be mailed to that individual.

(2) Materials may be delivered electronically following the requirements in paragraphs (d)(2)(i) and (ii) of this section.

(i) Without prior authorization, MA organizations may mail new and current enrollees a notice informing enrollees how to electronically access the following required materials: The Evidence of Coverage, Provider and Pharmacy Directories, and Formulary. The following requirements apply:

(A) The MA organization may mail one notice for all materials or multiple notices.

(B) Notices for prospective year documents may not be mailed prior to September 1 of each year, but must be sent in time for an enrollee to access the specified documents by October 15 of each year.

(C) The MA organization may send the notice throughout the year to new enrollees.

(D) The notice must include the website address to access the documents, the date the documents will be available if not currently available, and a phone number to request that hard copy documents be mailed.

(E) The notice must provide the enrollee with the option to request hardcopy materials. Requests may be materials specific, and must have the option of a one-time request or a permanent request that must stay in place until the enrollee chooses to receive electronic materials again.

(F) Hard copies of requested materials must be sent within three business days.

(ii) With prior authorization from the enrollee, MA organizations may provide any required material or content electronically. To do so, MA organizations must:

(A) Obtain prior consent from the enrollee. The consent must specify both the media type and the specific materials being provided in that media type.

(B) Provide instructions on how and when enrollees can access the materials.

(C) Have a process through which an enrollee can request hard copies be mailed, providing the beneficiary with the option of a one-time request or a permanent request (which must stay in place until the enrollee chooses to receive electronic materials again), and with the option of requesting hard copies for all or a subset of materials. Hard copies must be mailed within three business days.

(D) Have a process for automatic mailing of hard copies when electronic versions or the chosen media type is undeliverable.

(e) *CMS required materials and content.* The following are required materials that must be provided to current and or perspective enrollees, as applicable, in the form and manner outlined in this section:

(1) *Evidence of Coverage (EOC).* The EOC is a standardized communications material through which certain required information (under § 422.111(b)) must be provided annually.

(i) Must be provided to current enrollees of plan by October 15 of each Year.

(ii) Must be provided to new enrollees within ten (10) calendars days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(2) *Part C explanation of benefits (EOB).* The EOB is a model communications material through which plans must provide the information required under § 422.111(k). MA organizations may send this monthly or per claim with a quarterly summary.

(3) *Annual notice of change (ANOC).* The ANOC is a standardized marketing material through which plans must provide the information required under § 422.111(d)(2) annually.

(i) Must send for enrollee receipt no later than September 30 of each year.

(ii) Enrollees with an October 1, November 1, and December 1 effective date must receive within ten (10) calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(4) *Pre-Enrollment checklist (PECL).* The PECL is a standardized communications material that plans must provide to prospective enrollees with the enrollment form and Summary of Benefits (SB), so that the enrollees understand important plan benefits and rules. It references information on the following:

(i) The EOC.

(ii) Provider directory.

(iii) Pharmacy directory.

(iv) Formulary.

(v) Premiums/copayments/coinsurance.

(vi) Emergency/urgent coverage.

(vii) Plan-type rules.

(5) *Summary of Benefits (SB).* MA organizations must disseminate a summary of highly utilized coverage that include benefits and cost sharing to prospective Medicare beneficiaries, known as the SB. The SB is a model marketing material. It must be in a clear and accurate form.

(i) The SB must be provided with an enrollment form that meets the following:

(A) In hard copy with a paper enrollment form.

(B) For online enrollment, the SB must be made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where they can access the SB.

(ii) The SB must include the following information:

(A) Medical benefits:

(*1*) Monthly Plan Premium.

(*2*) Deductible/Out-of-pocket limits.

(*3*) Inpatient/Outpatient Hospital coverage.

(*4*) Ambulatory Surgical Center (ASC).

(*5*) Doctor Visits (Primary Care Providers and Specialists).

(*6*) Preventive Care.

(*7*) Emergency Care/Urgently Needed Services.

(*8*) Diagnostic Services/Labs/Imaging.

(*9*) Hearing Services/Dental Services/Vision Services.

(*10*) Mental Health Services.

(B) Prescription drug expense including (tiers/levels):

(*1*) Deductible, the initial coverage phase, coverage gap, and catastrophic coverage.

(*2*) A note that costs may differ based on pharmacy type or status (for example, preferred/non-preferred, mail order, long-term care (LTC) or home infusion, and 30- or 90-day supply), when applicable.

(C) For Medicare Medical Savings Account Plans (MSAs), the SB must include the following:

(*1*) The amount Medicare deposits into the beneficiaries MSA account.

(*2*) Language that the beneficiary pays nothing once the deductible is met.

(D) For dual eligible special needs plan (D–SNP)s, the SB must provide the Medicaid benefits to prospective enrollees. This may be done by either of the following:

(*1*) Including the Medicaid benefits in the SB.

(*2*) Providing a separate document with the Medicaid benefits that accompanies the SB.

(E) For D–SNPs open to dually eligible enrollees with differing levels of cost, the SB must:

(*1*) State how cost sharing and benefits differ depending on the level of Medicaid eligibility.

(*2*) Describe the Medicaid benefits, if any, provided by the plan.

(F) Fully integrated dual eligible SNPs (FIDE SNPs) and highly integrated D–SNPs, as defined in § 422.2, that provide Medicaid benefits have the option to display integrated Medicare and Medicaid benefits in the SB.

(G) MA organizations may include other health related benefits with the SB.

(6) *Enrollment/Election form.* This is model communications material through which plans must provide the information required under § 422.60(c).

(7) *Enrollment Notice.* This is a model communications material through which plans must provide the information required under § 422.60(e)(3).

(8) *Disenrollment Notice.* This is a model communications material through which plans must provide the information required under § 422.74(b).

(9) *Mid-Year Change Notification.* This is a model communications material through which plans must provide a notice to enrollees when there is a mid-year change in benefits or plan rules, under the following timelines:

(i) Notices of changes in plan rules, unless otherwise addressed elsewhere in this part, must be provided 30 days in advance.

(ii) For National Coverage Determination (NCD) changes announced or finalized less than 30 days before their effective date, a notification is required as soon as possible.

(iii) Mid-year NCD or legislative changes must be provided no later than 30 days after the NCD is announced.

(A) Plans may include the change in next plan mass mailing (for example, newsletter), provided it is within 30 days.

(B) The notice must also appear on the MA organization's website.

(10) *Non-renewal Notice.* This is a model communications material through which plans must provide the information required under § 422.506.

(i) The Non-renewal Notice must be provided at least 90 calendar days before the date on which the nonrenewal is effective. For contracts ending on December 31, the notice must be dated October 2 to ensure national consistency in the application of Medigap Guaranteed Issue (GI) rights to all enrollees, except for those enrollees in special needs plans (SNPs).

(ii) The Non-renewal Notice must do all of the following:

(A) Inform the enrollee that their plan will no longer be offered and told when their plan will end.

(B) Identify the last day the enrollee has to make a Medicare health plan selection and include any applicable open enrollment periods or special election periods or both (for example, Medicare open enrollment, non-renewal special election period).

(C) Explain what they must do to continue receiving Medicare coverage and what will happen if the enrollee chooses to do nothing.

(D) Include all available health plan options must be included in the enrollee's notice along with an explanation of how to obtain each option.

(E) Specify when coverage will start after a new Medicare plan is chosen.

(F) List 1–800–MEDICARE contact information together with other organizations that may be able to assist with comparing plans (for example, SHIPs).

(G) Explain Medigap to applicable enrollees and the special right to buy a Medigap policy and include a Medigap fact sheet with the non-renewal notice that explains Medigap coverage, policy, options to compare Medigap policies, and options to buy a Medigap policy.

(H) Include the MA organization's telephone number, TTY number, and hours and days of operation.

(11) *Provider Directory.* This is a model communications material through which plans must provide the information under § 422.111(b)(3). The Provider Directory must:

(i) Be provided to current enrollees of the plan by October 15 of each year.

(ii) Be provided to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(iii) Be provided to current enrollees upon request, within three 3 business days of the request.

(iv) Be updated any time the MA organization becomes aware of changes.

(A) Updates to the online provider directories must be completed within 30 days of receiving information requiring update.

(B) Updates to hardcopy provider directories must be completed within 30 days; hard copy directories that include separate updates via addenda are considered up-to-date.

(12) *Provider Termination Notice.* This is a model communications material through which plans must provide the information required under § 422.111(e). The provider termination notice must do both of the following:

(i) Be provided in hard copy.

(ii) Be sent via U.S. mail (first class postage is recommended, but not required).

(13) *Star Ratings Document.* This is a standardized marketing material through which Star Ratings information is conveyed to prospective enrollees.

(i) The Star Ratings Document is generated through HPMS.

(ii) The Star Ratings Document must be provided with an enrollment form, as follows:

(A) In hard copy with a paper enrollment form.

(B) For online enrollment, made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where they can access the Star Ratings Document.

(iii) New MA organization that have no Star Ratings are not required to provide the Star Ratings Document until the following contract year.

(iv) Updated Star Ratings must be used within 21 calendar days of release of updated information on Medicare Plan Finder.

(v) Updated Star Ratings must not be used until CMS releases Star Ratings on Medicare Plan Finder.

(14) *Organization Determination Notice.* This is a model communications material through which plans must provide the information under § 422.568.

(15) *Excluded Provider Notice.* This is a model communications material through which plans must notify members when a provider they use has been excluded from participating in the Medicare program based on an OIG exclusion or the CMS preclusion list.

(16) *Notice of Denial of Medical Coverage or Payment (NDMCP) (also known as the Integrated Denial Notice (IDN)).* This is a standardized material used to convey beneficiary appeal rights when a plan has denied a service as non-covered or excluded from benefits.

(17) *Notice of Medicare Non-Coverage (NOMNC).* This is a standardized material used to convey termination of previously-approved coverage.

(18) *Detailed Explanation of Non-Coverage (DENC).* This is a standardized material used to convey plan receipt of a request for an appeal on a beneficiary's behalf from the Beneficiary and Family Centered Care Quality Improvement Organization (BFCC–QIO).

(19) *Appointment of Representative (AOR).* This is a standardized material used to assign an individual to act on behalf of a beneficiary for the purpose of a specific appeal, grievance, or organization determination.

(20) *An Important Message From Medicare About Your Rights (IM).* This is a standardized material used to convey a beneficiary's discharge rights in an inpatient hospital setting.

(21) *Detailed Notice of Discharge Form (DND).* This is a standardized material used to convey a detailed explanation of an appellant's discharge rights from an inpatient hospital setting.

(22) *Medicare Outpatient Observation Notice (MOON).* This is a standardized material used to inform a beneficiary of outpatient status after an inpatient stay.

(23) *Appeal and Grievance Data Form.* This is a standardized material used to convey organization-specific grievance and appeals data.

(24) *Request for Administrative Law Judge (ALJ) Hearing.* This is a standardized material used to formally request a reconsideration of the independent review entity's determination.

(25) *Attorney Adjudicator Review in Lieu of ALJ Hearing.* This is a standardized material used to request that an attorney adjudicator review a previously determined decision rather than having an ALJ do so.

(26) *Notice of Right to an Expedited Grievance.* This is a model communications material used to convey a Medicare enrollee's rights to request that a decision be made on a grievance or appeal within a shorter timeframe.

(27) *Waiver of Liability Statement.* This is a model communications material used by providers to waive beneficiary liability for payment for denied services.

(28) *Notice of Appeal Status.* This is a model communications material used to inform a beneficiary of the denial of an appeal and additional appeal rights.

(29) *Notice of Dismissal of Appeal.* This is a model communications material used to convey the rationale by an MA organization to dismiss beneficiary's appeal.

(30) *Federal Contracting Statement.* This is model content through which plans must convey that they have a contract with Medicare and that enrollment in the plan depends on contract renewal.

(i) The Federal Contracting Statement must include all of the following:

(A) Legal or marketing name of the organization.

(B) Type of plan (for example, HMO, HMO SNP, PPO, PFFS, PDP).

(C) A statement that the organization has a contract with Medicare (when applicable, MA organizations may incorporate a statement that the organization has a contract with the state/Medicaid program).

(D) A statement that enrollment depends on contract renewal.

(ii) MA organizations must include the Federal Contracting Statement on all marketing materials with the exception of the following:

(A) Banners and banner-like advertisements.

(B) Outdoor advertisements.

(C) Text messages.

(D) Social media.

(31) *Star Ratings Disclaimer.* This is standardized content. The disclaimer consists of the statement ''Every year, Medicare evaluates plans based on a 5-star rating system,'' and must be present whenever Star Ratings are mentioned in marketing materials, with the exception of when Star Ratings are published on small objects (that is, a give-away items such as a pens or rulers).

(32) *Availability of Non-English Translations Disclaimer.* This is standardized content. The disclaimer consists of the statement ''ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1–XXX–XXX–XXXX (TTY: 1–XXX–XXX–XXXX).''

(i) The disclaimer must be placed in non-English languages that meet the 5 percent threshold for language translation under paragraph (a)(2) of this section.

(ii) The disclaimer must be added to all required materials in this section.

(33) *Accommodations Disclaimer.* This is standardized content. The disclaimer consists of the statement ''For accommodations of persons with special needs at meetings call '' and must be present on all advertisements and invitations to all events described under § 422.2264(c).

(34) *Mailing Statements.* This is standardized content. It consists of statements on envelopes that MA organizations must include when mailing information to current members, as follows:

(i) MA organizations must include the following statement when mailing information about the enrollee's current plan: ''Important [Insert Plan Name] information.''

(ii) MA organizations must include the following statement when mailing health and wellness information: ''Health and wellness or prevention information.''

(iii) The MA organization must include the plan name; however, if the plan name is elsewhere on the envelope, the plan name does not need to be repeated in the disclaimer.

(iv) Delegated or sub-contracted entities and downstream entities that conduct mailings on behalf of a multiple MA organizations must also comply with this requirement; however, they do not have to include a plan name.

(35) *Promotional Give-Away Disclaimer.* This is model content. The disclaimer consists of a statement that must make clear that there is no obligation to enroll in a plan, and must be included when offering a promotional give-away such as a drawing, prizes, or a free gift.

(36) *Provider Co-Branded Material Disclaimer.* This is standardized content. The disclaimer consists of the statement: ''Other Pharmacies/Physicians/Providers are available in our network,'' and must be included on materials that identify co-branding relationships with network provider or pharmacies. This disclaimer is not required when co-branding with a provider network or health system that represents 90 percent or more of the network as a whole.

(37) *Out of Network Non-Contracted Provider Disclaimer.* This is standardized content. The disclaimer consists of the statement: ''Out-of-network/non-contracted providers are under no obligation to treat <Plan> members, except in emergency situations. Please call our customer service number or see your Evidence of Coverage for more information, including the cost- sharing that applies to out-of-network services,'' and must be included whenever materials reference out-of-network/non-contracted providers.

(38) *NCQA SNP Approval Statement.* This is standardized content and must be used by SNPs who have received NCQA approval. It consists of the following statement: ''[Insert Plan Name] has been approved by the National Committee for Quality Assurance (NCQA) to operate as a Special Needs Plan (SNP) until [insert last contract year of NCQA approval] based on a review of [insert Plan Name's] Model of Care.'' MA organizations are prohibited from including numeric SNP approval scores, and no other language referencing NCQA approval may be used.

§ 422.2268 [Removed]

■ 58 Section 422.2268 is removed.

■ 59. Section 422.2274 is revised to read as follows:

§ 422.2274 Agent, broker, and other third party requirements.

If an MA organization uses agents and brokers to sell its Medicare plans, the requirements in paragraphs (a) through (e) of this section are applicable. If an MA organization makes payments to third parties, the requirements in paragraph (f) of this section are applicable.

(a) *Definitions.* For purposes of this section, the following definitions are applicable:

Compensation. (i) Includes monetary or non-monetary remuneration of any kind relating to the sale or renewal of a plan or product offered by an MA organization including, but not limited to the following:

(A) Commissions.

(B) Bonuses.

(C) Gifts.

(D) Prizes or Awards.

(E) Referral or Finder fees.

(ii) Does not include any of the following:

(A) Payment of fees to comply with State appointment laws, training, certification, and testing costs.

(B) Reimbursement for mileage to, and from, appointments with beneficiaries.

(C) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

Fair market value (FMV) means, for purposes of evaluating agent/broker compensation under the requirements of this section only, the amount that CMS determines could reasonably be expected to be paid for an enrollment or continued enrollment into an MA plan. FMV for an upcoming year is calculated by adding the current year FMV and the product of the current year FMV and MA Growth Percentage for aged and disabled beneficiaries, which is published for each year in the rate announcement issued pursuant to § 422.312.

Initial enrollment year means the first year that a beneficiary is enrolled in a plan vs. subsequent years (c.f., *renewal year*) that a beneficiary remains enrolled in a plan.

Like plan type means one of the following:

(i) PDP replaced with another PDP.

(ii) MA or MA–PD replaced with another MA or MA–PD.

(iii) Cost plan replaced with another cost plan.

Plan year and *enrollment year* mean the year beginning January 1 and ending December 31.

Renewal year means all years following the initial enrollment year in the same plan or in different plan that is a like plan type.

Unlike plan type means one of the following:

(i) An MA or, MA–PD plan to a PDP or Section 1876 Cost Plan.

(ii) A PDP to a Section 1876 Cost Plan or an MA or MA–PD plan.

(iii) A Section 1876 Cost Plan to an MA or MA–PD plan or PDP.

(b) *Agent/broker requirements.* Agents and brokers who represent MA organizations must follow the requirements in paragraphs (b)(1) through (3) of this section. Representation includes selling products (including Medicare Advantage plans, Medicare Advantage-Prescription Drug plans, Medicare Prescription Drug plans, and section 1876 Cost plans) as well as outreach to existing or potential beneficiaries and answering or potentially answering questions from existing or potential beneficiaries.

(1) Be licensed and appointed under State law (if required under applicable State law).

(2) Be trained and tested annually as required under paragraph (c)(4) of this section, and achieve an 85 percent or higher on all forms of testing.

(3) Secure and document a Scope of Appointment prior to meeting with potential enrollees.

(c) *MA organization oversight.* MA organizations must oversee first tier, downstream, and related entities that represent the MA organization to ensure agents/brokers abide by all applicable State and Federal laws, regulations, and requirements. MA organizations must do all of the following:

(1) As required under applicable State law, employ as marketing representatives only individuals who are licensed by the State to conduct marketing (as defined in this subpart) in that State, and whom the MA organization has informed that State it has appointed, consistent with the appointment process provided for under State law.

(2) As required under applicable State law, report the termination of an agent/broker to the State and the reason for termination.

(3) Report to CMS all enrollments made by unlicensed agents/brokers and for-cause terminations of agent/brokers.

(4) On an annual basis, provide agent/broker training and testing on Medicare rules and regulations, the plan products that agents and brokers will sell including any details specific to each plan product, and relevant State and Federal requirements.

(5) On an annual basis by the last Friday in July, report to CMS whether the MA organization intends to use employed, captive, and/or independent agents/brokers in the upcoming plan year and the specific rates or range of rates the plan will pay independent agents/brokers. Following the reporting deadline, MA organizations may not change their decisions related to agent/broker type, or their compensation rates and ranges, until the next plan year.

(6) On an annual basis by October 1, have in place full compensation structures for the following plan year. The structure must include details on compensation dissemination, including specifying payment amounts for initial enrollment year and renewal year compensation.

(7) Submit agent/broker marketing materials to CMS through HPMS prior to use, following the requirements for marketing materials in this subpart.

(8) Ensure agents and brokers do not charge beneficiaries a marketing fee.

(9) Establish and maintain a system for confirming that:

(i) Beneficiaries enrolled by agents/brokers understand the product, including the rules applicable under the plan.

(ii) Agent/brokers appropriately complete Scope of Appointment records for all marketing appointments (including telephonic and walk-in).

(10) Demonstrate that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(11) Must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

(d) *Compensation requirements.* MA organizations must ensure they meet the requirements in paragraphs (d)(1) through (5) of this section in order to pay compensation. These compensation requirements only apply to independent agent/brokers.

(1) *General rules.* (i) MA organizations may only pay agents/brokers who meet the requirements in paragraph (b) of this section.

(ii) MA organizations may determine, through their contracts, the amount of compensation to be paid, provided it does not exceed limitations outlined in this section.

(iii) MA organizations may determine their payment schedule (for example, monthly or quarterly). Payments (including payments for AEP enrollments) must be made during the year of the beneficiary's enrollment.

(iv) MA organizations may only pay compensation for the number of months a member is enrolled.

(2) *Initial enrollment year compensation.* For each enrollment in an initial enrollment year, MA organizations may pay compensation at or below FMV.

(i) MA organizations may pay either a full or pro-rated initial enrollment year compensation for:

(A) A beneficiary's first year of enrollment in any plan; or

(B) A beneficiary's move from an employer group plan to a non-employer group plan (either within the same parent organization or between parent organizations).

(ii) MA organizations must pay pro-rate initial enrollment year compensation for:

(A) A beneficiary's plan change(s) during their initial enrollment year.

(B) A beneficiary's selection of an ''unlike plan type'' change. In that case, the new plan would only pay the months that the beneficiary is enrolled, and the previous plan would recoup the months that the beneficiary was not in the plan.

(3) *Renewal compensation.* For each enrollment in a renewal year, MA plans may pay compensation at an amount up to 50 percent of FMV.

(i) MA plans may pay compensation for a renewal year:

(A) In any year following the initial enrollment year the beneficiary remains in the same plan; or

(B) When a beneficiary enrolls in a new ''like plan type''.

(ii) [Reserved]

(4) *Other compensation scenarios.* (i) When a beneficiary enrolls in an MA–PD, MA organizations may pay only the MA compensation (and not compensation for Part D enrollment under § 423.2274 of this chapter).

(ii) When a beneficiary enrolls in both a section 1876 Cost Plan and a stand-alone PDP, the 1876 Cost Plan sponsor may pay compensation for the cost plan enrollment and the Part D sponsor must pay compensation for the Part D enrollment.

(iii) When a beneficiary enrolls in a MA-only plan and a PDP plan, the MA plan sponsor may pay for the MA plan enrollment and the Part D plan may pay for the PDP plan enrollment.

(iv) When a beneficiary changes from two plans (for example, a MA plan and a stand-alone PDP) (dual enrollments) to one plan (MA–PD), the MA organization may only pay compensation at the renewal rate for the MA–PD product.

(5) *Additional compensation, payment, and compensation recovery requirements (Charge-backs).* (i) MA organizations must retroactively pay or recoup funds for retroactive beneficiary changes for the current and previous calendar years. MA organizations may choose to recoup or pay compensation for years prior to the previous calendar year, but they must do both (recoup amounts owed and pay amounts due during the same year).

(ii) Compensation recovery is required when:

(A) A beneficiary makes any plan change (regardless of the parent organization) within the first 3 months of enrollment (known as rapid disenrollment), except as noted in paragraph (d)(5)(iii) of this section.

(B) Any other time period a beneficiary is not enrolled in a plan, but the plan paid compensation based on that time period.

(iii) Rapid disenrollment compensation recovery does not apply when:

(A) A beneficiary enrolls effective October 1, November 1, or December 1 and subsequently uses the Annual Election Period to change plans for an effective date of January 1.

(B) A beneficiary's enrollment change is not in the best interests of the

Medicare program, including for the following reasons:

(*1*) Other creditable coverage (for example, an employer plan).

(*2*) Moving into or out of an institution.

(*3*) Gain or loss of employer/union sponsored coverage.

(*4*) Plan termination, non-renewal, or CMS imposed sanction.

(*5*) To coordinate with Part D enrollment periods or the State Pharmaceutical Assistance Program.

(*6*) Becoming LIS or dually eligible for Medicare and Medicaid.

(*7*) Qualifying for another plan based on special needs.

(*8*) Due to an auto, facilitated, or passive enrollment.

(*9*) Death.

(*10*) Moving out of the service area.

(*11*) Non-payment of premium.

(*12*) Loss of entitlement or retroactive notice of entitlement.

(*13*) Moving into a 5-star plan.

(*14*) Moving from an LPI plan into a plan with three or more stars.

(iv)(A) When rapid disenrollment compensation recovery applies, the entire compensation must be recovered.

(B) For other compensation recovery, plans must recover a pro-rated amount of compensation (whether paid for an initial enrollment year or renewal year) from an agent/broker equal to the number of months not enrolled.

(*1*) If a plan has paid full initial compensation, and the enrollee disenrolls prior to the end of the enrollment year, the total number of months not enrolled (including months prior to the effective date of enrollment) must be recovered from the agent/broker.

(*2*) Example: A beneficiary enrolls upon turning 65 effective April 1 and disenrolls September 30 of the same year. The plan paid full initial enrollment year compensation. Recovery is equal to 6/12ths of the initial enrollment year compensation (for January through March and October through December).

(e) *Payments to third parties.* (1) Payments made to third parties (that is, entities other than individual agents/brokers) for services other than enrollment of beneficiaries (for example, training customer service, agent recruitment, or operational overhead) must not exceed FMV.

(2) Administrative payments to third parties can be based on enrollment, provided payments are at or below FMV.

■ 60. Section 422.2420 is amended by revising paragraph (b)(2)(i) to read as follows:

§ 422.2420 Calculation of the medical loss ratio.

* * * * *

(b) * * *

(2) * * *

(i) Amounts that the MA organization pays (including under capitation contracts) for covered services, described at paragraph (a)(2) of this section, provided to all enrollees under the contract.

* * * * *

■ 61. Section 422.2440 is revised to read as follows:

§ 422.2440 Credibility adjustment.

(a) An MA organization may add the credibility adjustment specified under paragraph (e) of this section to a contract's MLR if the contract's experience is partially credible, as defined in paragraph (d)(1) of this section.

(b) An MA organization may not add a credibility adjustment to a contract's MLR if the contract's experience is fully credible, as defined in paragraph (d)(2) of this section.

(c) For those contract years for which a contract has non-credible experience, as defined in paragraph (d)(3) of this section, sanctions under § 422.2410(b) through (d) will not apply.

(d)(1) A contract's experience is partially credible if it is based on the experience of at least 2,400 member months and fewer than or equal to 180,000 member months.

(2) A contract's experience is fully credible if it is based on the experience of more than 180,000 member months.

(3) A contract's experience is non-credible if it is based on the experience of fewer than 2,400 member months.

(e)(1) The credibility adjustment for a partially credible MA contract, other than an MSA contract, is equal to the base credibility factor determined under paragraph (f) of this section.

(2) The credibility adjustment for a partially credible MA MSA contract is the product of the base credibility factor, as determined under paragraph (f) of this section, multiplied by the deductible factor, as determined under paragraph (g) of this section.

(f) The base credibility factor for partially credible experience is determined based on the number of member months for all enrollees under the contract and the factors shown in Table 1 of this section. When the number of member months used to determine credibility exactly matches a member month category listed in Table 1 of this section, the value associated with that number of member months is the base credibility factor. The base credibility factor for a number of member months between the values shown in Table 1 of this section is determined by linear interpolation.

(g) The deductible factor is based on the enrollment-weighted average deductible for all MSA plans under the MA MSA contract, where the deductible for each plan under the contract is weighted by the plan's portion of the total number of member months for all plans under the contract. When the weighted average deductible exactly matches a deductible category listed in Table 2 of this section, the value associated with that deductible is the deductible factor. The deductible factor for a weighted average deductible between the values shown in Table 2 of section is determined by linear interpolation.

TABLE 1 TO § 422.2440—BASE CREDIBILITY FACTORS FOR MA CONTRACTS

Member months	Base credibility factor (additional percentage points)
<2,400	N/A (Non-credible).
2,400	8.4%.
6,000	5.3%.
12,000	3.7%.
24,000	2.6%.
60,000	1.7%.
120,000	1.2%.
180,000	1.0%.
>180,000	0.0% (Fully credible).

TABLE 2 TO § 422.2440—DEDUCTIBLE FACTORS FOR MA MSA CONTRACTS

Weighted average deductible	Deductible factor
<$2,500	1.000
$2,500	1.164
$5,000	1.402
≥$10,000	1.736

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 62. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh.

■ 63. Section 423.4 is amended by adding definitions for ''Credible allegation of fraud'', ''Fraud hotline tip'', ''Inappropriate prescribing'', ''Parent organization'', and ''Substantiated or suspicious activities of fraud, waste, or abuse'' in alphabetical order to read as follows:

§ 423.4 Definitions.

* * * * *

Credible allegation of fraud means an allegation from any source, including but not limited to the following:

(1) Fraud hotline tips verified by further evidence.

(2) Claims data mining.

(3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability.

* * * * *

Fraud hotline tip is a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

* * * * *

Inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by Medicare Advantage (MA) organizations and Part D plan sponsors, there is an established pattern of potential fraud, waste, and abuse related to prescribing of opioids, as reported by the plan sponsors. Plan sponsors may consider any number of factors including, but not limited, to the following:

(1) Documentation of a patient's medical condition.

(2) Identified instances of patient harm or death.

(3) Medical records, including claims (if available).

(4) Concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm.

(5) Levels of morphine milligram equivalent (MME) dosages prescribed.

(6) Absent clinical indication or documentation in the care management plan or in a manner that may indicate diversion.

(7) State-level prescription drug monitoring program (PDMP) data.

(8) Geography, time, and distance between a prescriber and the patient.

(9) Refill frequency and factors associated with increased risk of opioid overdose.

* * * * *

Parent organization means the legal entity that exercises a controlling interest, through the ownership of shares, the power to appoint voting board members, or other means, in a Part D sponsor or MA organization, directly or through a subsidiary or subsidiaries, and which is not itself a subsidiary of any other legal entity.

* * * * *

Substantiated or suspicious activities of fraud, waste, or abuse means and includes, but is not limited to, allegations that a provider of services (including a prescriber) or supplier;

(1) Engaged in a pattern of improper billing;

(2) Submitted improper claims with suspected knowledge of their falsity;

(3) Submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or

(4) Is the subject of a fraud hotline tip verified by further evidence.

* * * * *

■ 64. Section 423.38 is amended by revising paragraph (c)(8) and adding paragraphs (c)(11) through (33) to read as follows:

§ 423.38 Enrollment periods.

* * * * *

(c) * * *

(8) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that the PDP sponsor offering the PDP substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to the following—

(i) Failure to provide the individual on a timely basis benefits available under the plan;

(ii) Failure to provide benefits in accordance with applicable quality standards; or

(iii) The PDP (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in communications as outlined in subpart V of this part.

* * * * *

(11) The individual is making an enrollment request into or out of an employer sponsored Part D plan, is disenrolling from a Part D plan to take employer sponsored coverage of any kind, or is disenrolling from employer sponsored coverage (including Consolidated Omnibus Budget Reconciliation Act (COBRA) coverage) to elect a Part D plan.

(i) This special election period (SEP) is available to individuals who have (or are enrolling in) an employer or union sponsored Part D plan and ends two months after the month the employer or union coverage of any type ends.

(ii) The individual may choose an effective date that is not earlier than the first of the month following the month in which the election is made and no later than up to three months after the month in which the election is made.

(12) The individual is enrolled in a Part D plan offered by a Part D plan sponsor that has been sanctioned by CMS and elects to disenroll from that plan in connection with the matter(s) that gave rise to that sanction.

(i) Consistent with the disclosure requirements at § 423.128(f), CMS may require the sponsor to notify current enrollees that if the enrollees believe they are affected by the matter(s) that gave rise to the sanction, the enrollees are eligible for a SEP to elect another PDP.

(ii) The SEP starts with the imposition of the sanction and ends when the sanction ends or when the individual makes an election, whichever occurs first.

(13) The individual is enrolled in a section 1876 cost contract that is non-renewing its contract for the area in which the enrollee resides.

(i) Individuals eligible for this SEP must meet Part D plan eligibility requirements.

(ii) This SEP begins December 8 of the then-current contract year and ends on the last day of February of the following year.

(14) The individual is disenrolling from a PDP to enroll in a Program of All-inclusive Care for the Elderly (PACE) organization or is enrolling in a PDP after disenrolling from a PACE organization.

(i) An individual who disenrolls from PACE has a SEP for 2 months after the effective date of PACE disenrollment to elect a PDP.

(ii) An individual who disenrolls from a PDP has a SEP for 2 months after the effective date of PDP disenrollment to elect a PACE plan.

(15) The individual moves into, resides in, or moves out of an institution, as defined by CMS, and elects to enroll in, or disenroll from, a Part D plan.

(16) The individual is not entitled to premium free Part A and enrolls in Part B during the General Enrollment Period for Part B (January through March) for an effective date of July 1st are eligible to request enrollment in a Part D plan that begins April 1st and ends June 30th, with a Part D plan enrollment effective date of July 1st.

(17) The individual belongs to a qualified State Pharmaceutical Assistance Program (SPAP) and is requesting enrollment in a Part D plan.

(i) The individual is eligible to make one enrollment election per year.

(ii) This SEP is available while the individual is enrolled in the SPAP and, upon loss of eligibility for SPAP benefits, for an additional 2 calendar months after either the month of the loss of eligibility or notification of the loss, whichever is later.

(18) The individual is enrolled in a Part D plan and elects to disenroll from that Part D plan to enroll in or maintain other creditable prescription drug coverage.

(19)(i) The individual is enrolled in a section 1876 cost contract and an optional supplemental Part D benefit under that contract and elects a Part D plan upon disenrolling from the cost contract.

(ii) The SEP begins the month the individual requests disenrollment from the cost contract and ends when the individual makes an enrollment election or on the last day of the second month following the month the cost contract enrollment ended, whichever is earlier.

(20) The individual is requesting enrollment in a Part D plan offered by a Part D plan sponsor with a Star Rating of 5 Stars. An individual may use this SEP only once for the contract year in which the Part D plan was assigned a 5-star overall performance rating, beginning the December 8 before that contract year through November 30 of that contract year.

(21)(i) The individual is a non-U.S. citizen who becomes lawfully present in the United States.

(ii) This SEP begins the month the enrollee attains lawful presence status and ends the earlier of when the individual makes an enrollment election or 2 calendar months after the month the enrollee attains lawful presence status.

(22) The individual was adversely affected by having requested, but not received, required notices or information in an accessible format, as outlined in section 504 of the Rehabilitation Act of 1973, within the same timeframe that the Part D plan sponsor or CMS provided the same information to individuals who did not request an accessible format.

(i) The SEP begins at the end of the election period during which the individual was seeking to make an election and the length is at least as long as the time it takes for the information to be provided to the individual in an accessible format.

(ii) Part D plan sponsors may determine eligibility for this SEP when the criterion is met, ensuring adequate documentation of the situation, including records indicating the date of the individual's request, the amount of time taken to provide accessible versions of materials and the amount of time it takes for the same information to be provided to an individual who does not request an accessible format.

(23) Individuals affected by a FEMA-declared weather-related emergency or major disaster are eligible for a SEP to make a Part D enrollment or disenrollment election. The SEP is available from the start of the incident period and for 4 calendar months after the start of the incident period. The individual is eligible for this SEP provided the individual—

(i)(A) Resides, or resided at the start of the incident period, in an area for which Federal Emergency Management Agency (FEMA) has declared an emergency or a major disaster and has designated affected counties as being eligible to apply for individual or public level assistance; or

(B) Does not reside in the affected areas but relies on help making healthcare decisions from one or more individuals who reside in the affected areas; and

(ii) Was eligible for an election period at the time of incident period; and

(iii) Did not make an election during that election period due to the weather-related emergency or major disaster.

(24) The individual is using the SEP at § 422.62(b)(8) of this chapter to disenroll from a MA plan that includes Part D benefits.

(i) This SEP permits a one-time election to enroll in a Part D plan.

(ii) This SEP begins upon disenrollment from the MA plan and continues for 2 calendar months.

(25)(i) An individual using the MA Open Enrollment Period for Institutionalized Individuals (OEPI) to disenroll from a MA plan that includes Part D benefits plan is eligible for a SEP to request enrollment in a Part D plan.

(ii) The SEP begins with the month the individual requests disenrollment from the MA plan and ends on the last day of the second month following the month MA enrollment ended.

(26) An individual using the Medicare Advantage Open Enrollment Period (MA OEP) to elect original Medicare is eligible for a SEP to make a Part D enrollment election.

(27)(i) The individual is enrolled in a MA special needs plan (SNP) and is no longer eligible for the SNP because he or she no longer meets the specific special needs status.

(ii) The individual may request enrollment in a Part D plan that begins the month the individual's special needs status changes and ends the earlier of when he or she makes an election or 3 months after the effective date of involuntary disenrollment from the SNP.

(28) The individual is found, after enrollment into a Chronic Care SNP, not to have the required qualifying condition.

(i) This individual is eligible to enroll prospectively in a Part D plan.

(ii) This SEP begins when the MA organization notifies the individual of the lack of eligibility for the Chronic Care SNP and extends through the end of that month and the following 2 calendar months.

(iii) The SEP ends when the individual makes an enrollment election or on the last day of the second of the 2 calendar months following notification of the lack of eligibility, whichever occurs first.

(29) The individual uses the SEP at § 422.62(b)(15) of this chapter to enroll in a MA Private Fee-for-Service plan without Part D benefits, or enrolls in a section 1876 cost plan, is eligible to request enrollment in a PDP or the cost plan's optional supplemental Part D benefit, if offered.

(i) This SEP begins the month the individual uses the SEP at § 422.62(b)(15) of this chapter and continues for 2 additional months.

(ii) [Reserved]

(30) An individual who uses the SEP at § 422.62(b)(23) of this chapter to disenroll from a MA plan is eligible to request enrollment in a PDP.

(i) This SEP begins the month the individual is notified of eligibility for the SEP at § 422.62(b)(23) of this chapter and continues for an additional 2 calendar months.

(ii) This SEP permits one enrollment into a PDP.

(iii) This SEP ends when the individual has enrolled in the PDP.

(iv) An individual may use this SEP to request enrollment in a PDP subsequent to having submitted a disenrollment to the MA plan or may simply request enrollment in the PDP, resulting in automatic disenrollment from the MA plan.

(31) The individual is enrolled in a plan offered by a Part D plan sponsor that has been placed into receivership by a state or territorial regulatory authority. The SEP begins the month the receivership is effective and continues until it is no longer in effect or until the enrollee makes an election, whichever occurs first. When instructed by CMS, the MA plan that has been placed under receivership must notify its enrollees, in the form and manner directed by CMS, of the enrollees' eligibility for this SEP and how to use the SEP.

(32) The individual is enrolled in a plan that has been identified with the low performing icon in accordance with § 423.186(h)(1)(ii). This SEP exists while the individual is enrolled in the low performing Part D plan.

(33) The individual meets other exceptional circumstances as CMS may provide.

* * * * *

■ 65. Section 423.40 is amended by revising paragraph (c) to read as follows:

§ 423.40 Effective dates.

* * * * *

(c) *Special enrollment periods.* For an enrollment or change of enrollment in Part D made during a special enrollment period specified in § 423.38(c), the coverage or change in coverage is effective the first day of the calendar month following the month in which the election is made, unless otherwise noted.

* * * * *

■ 66. Section 423.100 is amended—

■ a. In the definition of ''Applicable drug'' by revising paragraph (1)(ii);

■ b. In the definition of ''Exempted beneficiary'' by:

■ i. Removing the word ''or'' at the end of paragraph (2);

■ ii. Removing the period at the end of paragraph (3) and adding ''; or'' in its place; and

■ iii. Adding paragraph (4); and

■ c. By revising the definition of ''Potential at-risk beneficiary''.

The revisions and addition read as follows:

§ 423.100 Definitions.

* * * * *

Applicable drug * * *

(1) * * *

(ii) In the case of a biological product, licensed under section 351 of the Public Health Service Act (other than, with respect to a plan year before 2019), a product licensed under subsection (k) of such section 351); and

* * * * *

Exempted beneficiary * * *

(4) Has sickle cell disease.

* * * * *

Potential at-risk beneficiary means a Part D eligible individual who meets any of the following:

(1) Is identified using clinical guidelines (as defined in this section).

(2) Who is identified by CMS as having a history of opioid-related overdose on the following basis:

(i) At least one recent Medicare fee-for-service claim has been submitted that contains a principal diagnosis code indicating opioid overdose.

(ii) At least one recent PDE for an opioid medication has been submitted.

(3) With respect to whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as a potential at-risk beneficiary (as defined in paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon disenrollment.

* * * * *

■ 67. Section 423.104 is amended by adding paragraph (d)(2)(iv) to read as follows:

§ 423.104 Requirements related to qualified prescription drug coverage.

* * * * *

(d) * * *

(2) * * *

(iv) Specialty tier means a formulary cost sharing tier dedicated to high-cost Part D drugs with ingredient costs for a 30-day equivalent supply (as described in paragraph (d)(2)(iv)(A)(*2*) of this section) that are greater than the specialty tier cost threshold specified in paragraph (d)(2)(iv)(A) of this section.

(A) *Specialty-tier cost threshold.* CMS sets the specialty-tier cost threshold for a plan year in accordance with this paragraph (d)(2)(iv)(A), using the following steps:

(*1*) *30-day equivalent ingredient cost.* Using the PDE data as specified in paragraph (d)(2)(iv)(C) of this section, CMS uses the ingredient cost reflected on the prescription drug event (PDE) to determine the ingredient cost in dollars for a 30-day equivalent supply of the Part D drug.

(*2*) *30-day equivalent supply.* CMS determines the 30-day equivalent supply as follows: If the days' supply reported on a PDE is less than or equal to 34, the number of 30-day equivalent supplies equals one. If the days' supply reported on a PDE is greater than 34, the number of 30-day equivalent supplies is equal to the number of days' supply reported on each PDE divided by 30.

(*3*) *Top 1 percent.* CMS determines the amount that equals the lowest 30-day equivalent ingredient cost that is within the top 1 percent of all 30-day equivalent ingredient costs reflected in the PDE data.

(*4*) *Determination.* Except as provided in paragraph (d)(2)(iv)(B) of this section, the amount determined in paragraph (d)(2)(iii) of this section is the specialty-tier cost threshold for the plan year.

(*5*) *Claims history.* Except for newly FDA-approved Part D drugs only recently available on the market for which Part D sponsors would have little or no claims data, CMS approves placement of a Part D drug on a specialty tier when that Part D sponsor's claims data from the time period specified in paragraph (d)(2)(iv)(C) of this section demonstrates that greater than 50 percent of the Part D sponsor's PDEs for a given Part D drug, when adjusted for 30-day equivalent supplies, have ingredient costs for 30-day equivalent supplies, as described in paragraph (d)(2)(iv)(A)(*2*) of this section, that exceed the specialty-tier cost threshold.

(B) *Limit on specialty-tier cost threshold adjustment.* (*1*) CMS increases the specialty-tier cost threshold for a plan year only if the amount determined in paragraph (d)(2)(iv)(A)(*3*) of this section for a plan year is at least 10 percent above the specialty tier cost threshold for the prior plan year.

(*2*) If an increase is made in accordance with this paragraph (d)(2)(iv)(B), CMS rounds the amount determined in paragraph (d)(2)(iv)(A)(*3*) of this section to the nearest $10, and the resulting dollar amount is the specialty-tier cost threshold for the plan year.

(C) *Data used to determine the specialty-tier cost threshold.* CMS uses PDEs from the plan year that ended 12 months prior to the applicable plan year.

(D) *Maximum number of specialty tiers and maximum allowable cost sharing.* A Part D plan may maintain up to two specialty tiers. CMS sets the maximum allowable cost sharing for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost sharing specialty tier as follows:

(*1*) For Part D plans with the full deductible provided under the Defined Standard benefit, as specified in paragraph (d)(1) of this section, 25 percent coinsurance.

(*2*) For Part D plans with no deductible, 33 percent coinsurance.

(*3*) For Part D plans with a deductible that is greater than $0 and less than the deductible provided under the Defined Standard benefit, a coinsurance percentage that is determined by subtracting the plan's deductible from 33 percent of the initial coverage limit (ICL) under section 1860D–2(b)(3) of the Act, dividing this difference by the difference between the ICL and the plan's deductible, and rounding to the nearest 1 percent.

* * * * *

■ 68. Section 423.128 is amended by—

■ a. Revising paragraph (a)(1);

■ b. Adding paragraph (b)(11);

■ c. Revising paragraphs (d)(1)(i), (ii), and (iii); and

■ d. Adding paragraphs (d)(1)(v) and (vi) and (d)(4) and (5).

The revisions and additions read as follows:

§ 423.128 Dissemination of Part D plan information.

(a) * * *

(1) To each enrollee of a Part D plan offered by the Part D sponsor under this

part, except as provided in paragraph (b)(11)(ii) of this section;

* * * * *

(b) * * *

(11) *Opioid information.* (i) Subject to paragraph (b)(11)(ii) of this section, for plan year 2021 and each subsequent year, a Part D sponsor must disclose to each enrollee identified in paragraph (b)(11)(ii) of this section at least once per year the following:

(A) The risks associated with prolonged opioid use.

(B) Coverage of non-pharmacological therapies, devices, and non-opioid medications—

(*1*) In the case of an MA–PD, under such plan; and

(*2*) In the case of a PDP, under such plan and Medicare Parts A and B.

(ii) The Part D sponsor may elect to, in lieu of disclosing the information described in paragraph (b)(11)(i) of this section to each enrollee under each plan offered by the Part D sponsor under this part, disclose such information to a subset of enrollees, such as enrollees who have been prescribed an opioid in the previous 2-year period.

* * * * *

(d) * * *

(1) * * *

(i)(A) Is open at least from 8:00 a.m. to 8:00 p.m. in all regions served by the Part D plan.

(B) Any call center serving pharmacists or pharmacies must be open so long as any network pharmacy in that region is open.

(ii) At a minimum provides customer telephone service, including to pharmacists, in accordance with the following business practices:

(A) Limits average hold time to 2 minutes. The hold time is defined as the time spent on hold by callers following the interactive voice response (IVR) system, touch-tone response system, or recorded greeting, before reaching a live person.

(B) Answers 80 percent of incoming calls within 30 seconds after the Interactive Voice Response (IVR), touch-tone response system, or recorded greeting interaction.

(C) Limits the disconnect rate of all incoming calls to 5 percent. The disconnect rate is defined as the number of calls unexpectedly dropped divided by the total number of calls made to the customer call center.

(iii)(A) Provides interpreters for non-English speaking and limited English proficient (LEP) individuals.

(B) Interpreters must be available within 8 minutes of reaching the customer service representative and be made available at no cost to the caller.

* * * * *

(v)(A) Responds to TTY-to-TTY calls as defined in 47 CFR part 64, subpart F, in accordance with the mandatory minimum standards delineated in 47 CFR 64.604.

(B) Provides effective real-time communication with individuals using auxiliary aids and services, including TTYs and all forms of Federal Communication Commission-approved telecommunications relay systems, when using automated-attendant systems. See 28 CFR 35.161 and 36.303(d).

(vi) Provides the information described in paragraph (d)(4) of this section to enrollees who call the customer service call center.

* * * * *

(4) A Part D sponsor must implement, and make available directly to enrollees, in an easy to understand manner, the following accurate, timely, clinically appropriate, patient-specific formulary and benefit real-time information in their beneficiary-specific portal or computer application:

(i) Enrollee cost sharing amounts.

(ii) Clinically appropriate formulary medication alternatives for a given condition, which are not excluded based on cost implications.

(iii) Formulary status, including utilization management requirements applicable to each alternative medication, as appropriate for each enrollee and medication presented.

(5) The Part D sponsor may provide rewards and incentives to enrollees who use the beneficiary real time benefit tool (RTBT) described in paragraph (d)(4) of this section, provided the rewards and incentives comply with the requirements in paragraphs (d)(5)(i) through (iii) of this section, and the rewards and incentives information is made available to CMS upon request. Use is defined as logging into the RTBT, via portal or computer application, or calling the customer service call center to obtain the information described in paragraph (d)(4) of this section. The rewards and incentives must meet the following:

(i) Be of nominal value, both individually and in the aggregate.

(ii) Be offered to enrollees for no more than one login per month.

(iii) Be designed so that all enrollees are eligible to earn rewards and incentives, and that there is no discrimination based on race, national origin, gender, disability, chronic disease, health status, or basis prohibited by any applicable law.

(iv) Not be offered in the form of cash or other cash equivalents.

(v) Not be used to target potential enrollees.

(vi) Be earned solely for logging onto the beneficiary RTBT and not for any other purpose.

(vii) Otherwise comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil money penalty prohibiting inducements to beneficiaries.

* * * * *

■ 69. Section 423.153 is amended—

■ a. By revising the section heading;

■ b. In paragraph (a) by removing the phrase ''A Part D plan sponsor may establish a drug management'' and adding in its place the phrase ''No later than January 1, 2022, a Part D plan sponsor must have established a drug management'';

■ c. By adding paragraphs (d)(1)(vii)(E) and (F);

■ d. By revising paragraph (d)(2);

■ e. In paragraph (f)(3)(ii) introductory text by removing the phrase ''paragraphs (f)(10) and (11) of this section'' and adding in its place the phrase ''paragraphs (f)(9) through (13) of this section'';

■ f. In paragraph (f)(4)(ii)(A) by:

■ i. Removing the phrase ''paragraph (f)(2)(ii)(B) of this section'' and adding in its place the phrase ''paragraph (f)(3)(ii)(A) of this section'';

■ ii. Removing the phrase ''paragraph (f)(4)(i)(B) of this section'' and adding in its place the phrase ''paragraph (f)(2)(i)(B) of this section'';

■ g. Revising paragraphs (f)(5)(ii)(C)(*3*), (f)(6)(ii)(C)(*4*), and (f)(8)(i);

■ h. In paragraph (f)(15)(ii)(C) by removing the phrase ''any potential at-risk beneficiary'' and adding in its place the phrase ''any potential at-risk beneficiary or at-risk beneficiary''; and

■ i. By revising the heading of paragraph (g).

The revisions and additions read as follows:

§ 423.153 Drug utilization management, quality assurance, medication therapy management programs (MTMPs), and access to Medicare Parts A and B claims data extracts.

* * * * *

(d) * * *

(1) * * *

(vii) * * *

(E) For enrollees targeted in paragraph (d)(2) of this section, provide at least annually as part of the comprehensive medication review, a targeted medication review, or another follow up service, information about safe disposal of prescription drugs that are controlled substances, drug take back programs, in-home disposal and cost-effective means to safely dispose of such drugs.

(F) The information to be provided under paragraph (d)(1)(vii)(E) of this

section must comply with all requirements of § 422.111(j) of this chapter.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the MTMP described in paragraph (d)(1) of this section are enrollees in the sponsor's Part D plan who meet the characteristics of at least one of the following two groups:

(i)(A) Have multiple chronic diseases, with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment;

(B) Are taking multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment; and

(C) Are likely to incur the following annual Part D drug costs:

(*1*) For 2011, costs for covered Part D drugs greater than or equal to $3,000.

(*2*) For 2012 and subsequent years, costs for covered Part D drugs in an amount greater than or equal to $3,000 increased by the annual percentage specified in § 423.104(d)(5)(iv); or

(ii) Beginning January 1, 2021, are at-risk beneficiaries as defined in § 423.100.

* * * * *

(f) * * *

(5) * * *

(ii) * * *

(C) * * *

(*3*) An explanation of the beneficiary's right to a redetermination if the sponsor issues a determination that the beneficiary is an at-risk beneficiary and the standard and expedited redetermination processes described at §§ 423.582 and 423.584, including notice that if on redetermination the plan sponsor affirms its denial, in whole or in part, the case must be automatically forwarded to the independent review entity contracted with CMS for review and resolution.

(6) * * *

(ii) * * *

(C) * * *

(*4*) An explanation of the beneficiary's right to a redetermination under § 423.580, including all of the following:

(*i*) A description of both the standard and expedited redetermination processes.

(*ii*) The beneficiary's right to, and conditions for, obtaining an expedited redetermination.

(*iii*) Notice that if on redetermination the plan sponsor affirms its denial, in whole or in part, the case must be automatically forwarded to the independent review entity contracted with CMS for review and resolution.

* * * * *

(8) * * *

(i) Subject to paragraph (f)(8)(ii) of this section, a Part D sponsor must provide the second notice described in paragraph (f)(6) of this section or the alternate second notice described in paragraph (f)(7) of this section, as applicable, on a date that is not less than 30 days after the date of the initial notice described in paragraph (f)(5) of this section and not more than the earlier of the following two dates:

(A) The date the sponsor makes the relevant determination.

(B) Sixty days after the date of the initial notice described in paragraph (f)(5) of this section.

* * * * *

(g) *Prescription drug plan sponsors' access to Medicare Parts A and B claims data extracts*—* * *

* * * * *

■ 70. Section 423.182 is amended—

■ a. In paragraph (a) by adding a definition for ''Tukey outer fence outliers'' in alphabetical order; and

■ b. By revising paragraphs (b)(3)(ii)(A) and (B).

The additions and revisions read as follows:

§ 423.182 Part D Prescription Drug Plan Quality Rating System.

(a) * * *

Tukey outer fence outliers are measure scores that are below a certain point (first quartile − 3.0 × (third quartile × first quartile)) or above a certain point (third quartile + 3.0 × (third quartile − first quartile)).

(b) * * *

(3) * * *

(ii) * * *

(A)(*1*) For the first year after consolidation, CMS uses enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except survey-based measures and call center measures. The survey-based measures would use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures would use average enrollment during the study period.

(*2*) For contract consolidations approved on or after January 1, 2021, if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 423.184(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

(B)(*1*) For the second year after consolidation, CMS uses the enrollment-weighted measure scores using the July enrollment of the measurement year of the consumed and surviving contracts for all measures except those from CAHPS. CMS ensures that the CAHPS survey sample includes enrollees in the sample frame from both the surviving and consumed contracts.

(*2*) For contract consolidations approved on or after January 1, 2021, for all measures except CAHPS if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 423.184(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

* * * * *

■ 71. Section 423.184 is amended by revising paragraph (g)(1)(ii)(A) to read as follows:

§ 423.184 Adding, updating, and removing measures.

* * * * *

(g) * * *

(1) * * *

(ii) * * *

(A)(*1*) The data submitted for the Timeliness Monitoring Project (TMP) or audit that aligns with the Star Ratings year measurement period is used to determine the scaled reduction.

(*2*) For contract consolidations approved on or after January 1, 2021, if there is a contract consolidation as described at § 423.182(b)(3), the TMP or audit data are combined for the consumed and surviving contracts before the methodology, as provided in paragraphs (g)(1)(ii)(B) through (M) of this section, is applied.

* * * * *

■ 72. Section 423.186 is amended—

■ a. By revising paragraph (a)(2)(i);

■ b. In paragraphs (e)(1)(iii) and (iv) by removing the phrase ''weight of 2'' and adding in its place ''weight of 4''; and

■ c. By adding a sentence to the end of paragraph (i)(6).

The revision and additions read as follows:

§ 423.186 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data, and a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next. Prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute

percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

* * * * *

(i) * * *

(6) * * * Missing data includes data where there is a data integrity issue as defined at § 423.184(g)(1).

* * * * *

■ 73. Section 423.265 is amended by revising paragraph (b)(2) to read as follows:

§ 423.265 Submission of bids and related information.

* * * * *

(b) * * *

(2) *Limit on number of plan offerings.* Potential Part D sponsors' bid submissions may include no more than three stand-alone prescription drug plan offerings in a service area and must include only one basic prescription drug plan offering.

* * * * *

■ 74. Section 423.286 is amended by revising paragraph (d)(4)(ii) to read as follows:

§ 423.286 Rules regarding premiums.

* * * * *

(d) * * *

(4) * * *

(ii) *Calculating the income-related monthly adjustment amount.* The income-related monthly adjustment is equal to the product of the standard base beneficiary premium, as determined under paragraph (c) of this section, and the ratio of the applicable premium percentage specified in 20 CFR 418.2120, reduced by 25.5 percent; divided by 25.5 percent (that is, premium percentage − 25.5 percent)/ 25.5 percent).

* * * * *

■ 75. Section 423.329 is amended by revising paragraph (b)(4) to read as follows:

§ 423.329 Determination of payments.

* * * * *

(b) * * *

(4) *Publication.* CMS publishes the risk adjustment factors established under paragraph (b)(1) of this section for the upcoming calendar year in the Advance Notice and Rate Announcement publications specified under § 422.312 of this chapter.

* * * * *

■ 76. Section 423.502 is amended by adding paragraphs (b)(1)(i) and (ii) to read as follows:

§ 423.502 Application requirements.

* * * * *

(b) * * *

(1) * * *

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) of this section if during the applicable review period the applicant does any of the following:

(A) Was subject to the imposition of an intermediate sanction or civil money penalty under to subpart O of this part.

(B) Failed to maintain a Part D summary rating score of at least three stars consistent with § 423.505(b)(26).

(C) Failed to maintain a fiscally sound operation consistent with the requirements of § 423.505(b)(23).

(ii) CMS may deny an application submitted by an organization that does not hold a Part D contract at the time of the submission when the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (b)(1)(i) of this section.

* * * * *

■ 77. Section 423.503 is amended by revising paragraph (a)(3) to read as follows:

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

(a) * * *

(3) CMS does not approve an application when it would result in the applicant's parent organization, directly or through its subsidiaries, holding more than one PDP sponsor contract in the PDP Region for which the applicant is seeking qualification as a PDP sponsor.

* * * * *

■ 78. Section 423.504 is amended by adding paragraphs (b)(4)(vi)(G)(*4*) through (*7*) to read as follows:

§ 423.504 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(G) * * *

(*4*) The Part D plan sponsor must have procedures to identify, and must report to CMS or its designee either of the following, in the manner described in paragraphs (b)(4)(vi)(G)(*4*) through (*6*) of this section:

(*i*) Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o)(1) of the Act.

(*ii*) Any information related to the inappropriate prescribing of opioids and concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan.

(*5*) The Part D plan sponsor must submit the data elements, as specified in this section, in the program integrity portal when reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies; information related to the inappropriate prescribing of opioids and concerning investigations and credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan sponsor; or if the plan reports a referral, through the portal, of substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste or abuse to initiate or assist with investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners. The data elements, as applicable, are as follows:

(*i*) Date of Referral.

(*ii*) Part C or Part D Issue.

(*iii*) Complainant Name.

(*iv*) Complainant Phone.

(*v*) Complainant Fax.

(*vi*) Complainant Email.

(*vii*) Complainant Organization Name.

(*viii*) Complainant Address.

(*ix*) Complainant City.

(*x*) Complainant State.

(*xi*) Complainant Zip.

(*xii*) Plan Name/Contract Number.

(*xiii*) Plan Tracking Number.

(*xiv*) Parent Organization.

(*xv*) Pharmacy Benefit Manager.

(*xvi*) Beneficiary Name.

(*xvii*) Beneficiary Phone.

(*xviii*) Beneficiary Health Insurance Claim Number (HICN).

(*xix*) Beneficiary Medicare Beneficiary Identifier (MBI).

(*xx*) Beneficiary Address.

(*xxi*) Beneficiary City.

(*xxii*) Beneficiary State.

(*xxiii*) Beneficiary Zip.

(*xxiv*) Beneficiary Date of Birth (DOB).

(*xxv*) Beneficiary Primary language.

(*xxvi*) Beneficiary requires Special Accommodations. If Yes, Describe.

(*xxvii*) Beneficiary Medicare Plan Name.

(*xxviii*) Beneficiary Member ID Number.

(*xxix*) Whether the Beneficiary is a Subject.

(*xxx*) Did the complainant contact the beneficiary. If Yes, is there a Report of the Contact?

(*xxxi*) Subject Name.
(*xxxii*) Subject Tax Identification Number (TIN).
(*xxxiii*) Does the Subject have Multiple TIN's. If Yes, provide.
(*xxxiv*) Subject NPI.
(*xxxv*) Subject DEA Number.
(*xxxvi*) Subject Medicare Provider Number.
(*xxxvii*) Subject Business.
(*xxxviii*) Subject Phone Number.
(*xxxix*) Subject Address.
(*xl*) Subject City.
(*xli*) Subject State.
(*xlii*) Subject Zip.
(*xliii*) Subject Business or Specialty Description.
(*xliv*) Secondary Subject Name.
(*xlv*) Secondary Subject Tax Identification Number (TIN)
(*xlvi*) Does the Secondary Subject have Multiple TIN's. If Yes, provide.
(*xlvii*) Secondary Subject NPI.
(*xlviii*) Secondary Subject DEA Number.
(*xlix*) Secondary Subject Medicare Provider Number.
(*l*) Secondary Subject Business.
(*li*) Secondary Subject Phone Number.
(*lii*) Secondary Subject Address.
(*liii*) Secondary Subject City.
(*liv*) Secondary Subject State.
(*lv*) Secondary Subject Zip.
(*lvi*) Secondary Subject Business or Specialty Description.
(*lvii*) Complaint Prior MEDIC Case Number.
(*lviii*) Period of Review.
(*lix*) Complaint Potential Medicare Exposure.
(*lx*) Whether Medical Records are Available.
(*lxi*) Whether Medical Records were Reviewed.
(*lxii*) Whether the submission has been Referred to Law Enforcement. Submission Accepted? If so, provide Date Accepted.
(*lxiii*) What Law Enforcement Agency(ies) has it been Referred to.
(*lxiv*) Whether HPMS Analytics and Investigations Collaboration Environment for Fraud, Waste, and Abuse (AICE–FWA) was Used.
(*lxv*) Whether the submission has indicated Patient Harm or Potential Patient Harm.
(*lxvi*) Whether the submission has been Referred. If so, provide Date Accepted.
(*lxvii*) What Agency was it Referred to.
(*lxviii*) Description of Allegations/Plan Sponsor Findings.

(*6*)(*i*) The plan sponsor is required to notify the Secretary, or its designee, of a payment suspension described in paragraph (b)(4)(vi)(G)(*4*) of this section 14 days prior to implementation of the payment suspension.

(*ii*) The plan sponsor is required to submit the information described in paragraph (b)(4)(vi)(G)(*4*)(*ii*) of this section no later than January 15, April 15, July 15, and October 15 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. For the first reporting period (January 15, 2021), the reporting will reflect the data gathered and analyzed for the previous quarter in the calendar year (October 1–December 31).

(*7*)(*i*) CMS provides plan sponsors with data report(s) or links to the information described in paragraphs (b)(4)(vi)(G)(*4*)(*i*) and (*ii*) of this section no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30.

(*ii*) Include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders.

(*iii*) Are anonymized information submitted by plans without identifying the source of such information.

(*iv*) For the first quarterly report (April 15, 2021), that the report reflect the data gathered and analyzed for the previous quarter submitted by the plan sponsors on January 15, 2021.

* * * * *

■ 79. Section 423.505 is amended by revising paragraph (b)(22) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(22) Through the CMS complaint tracking system, address and resolve complaints received by CMS against the MA organization.

* * * * *

■ 80. Section 423.514 is amended by redesignating paragraph (a)(5) as paragraph (a)(6) and adding a new paragraph (a)(5) to read as follows:

§ 423.514 Validation of Part D reporting requirements.

(a) * * *

(5) Pharmacy performance measures.

* * * * *

■ 81. Section 423.560 is amended by—
■ a. Removing the definition of ''Appointed representative'';
■ b. Adding the definition of ''Representative'' in alphabetical order; and
■ c. Revising the definition of ''Specialty tier''.

The addition and revision read as follows:

§ 423.560 Definitions.

* * * * *

Representative means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process. Unless otherwise stated in this subpart, the representative has all of the rights and responsibilities of an enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M, of this chapter.

Specialty tier has the meaning given the term in § 423.104.

■ 82. Section 423.566 is amended by revising paragraph (c)(2) to read as follows:

§ 423.566 Coverage determinations.

* * * * *

(c) * * *

(2) The enrollee's representative, on behalf of the enrollee; or

* * * * *

■ 83. Section 423.568 is amended by adding paragraphs (i) through (m) to read as follows:

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

* * * * *

(i) *Dismissing a request.* The Part D plan sponsor may dismiss a coverage determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the individual making the request is not permitted to request a coverage determination under § 423.566(c).

(2) When the Part D plan sponsor determines the party failed to make out a valid request for a coverage determination that substantially complies with paragraph (a) of this section.

(3) When an enrollee or the enrollee's representative files a request for a coverage determination, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) The enrollee's representative, if any, does not wish to pursue the request for coverage.

(4) When a party filing the coverage determination request submits a timely written request for withdrawal of the request for a coverage determination with the Part D plan sponsor.

(j) *Notice of dismissal.* The Part D plan must mail or otherwise transmit a written notice of the dismissal of the coverage determination request to the parties. The notice must state the all of the following:

(1) The reason for the dismissal.

(2) The right to request that the MA organization vacate the dismissal action.

(3) The right to request reconsideration of the dismissal.

(k) *Vacating a dismissal.* If good cause is established, the Part D plan sponsor may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(l) *Effect of dismissal.* The Part D plan sponsor's dismissal is binding unless it is modified or reversed by the Part D plan sponsor or vacated under paragraph (k) of this section.

(m) *Withdrawing a request.* A party that requests a coverage determination may withdraw its request at any time before the decision is issued by filing a written request with the Part D plan sponsor.

■ 84. Section 423.570 is amended by adding paragraph (f) to read as follows:

§ 423.570 Expediting certain coverage determinations.

* * * * *

(f) *Dismissing a request.* The Part D plan sponsor may dismiss an expedited coverage determination in accordance with § 423.568.

■ 85. Section 423.578 is amended—

■ a. By revising paragraph (a)(6)(iii); and

■ b. In paragraph (b)(4) by removing the phrase ''the enrollee's appointed representative'' and adding in its place the phrase ''the enrollee's representative''.

The revision reads as follows:

§ 423.578 Exceptions process.

(a) * * *

(6) * * *

(iii) If a Part D plan sponsor maintains one or two specialty tiers, as defined in § 423.104, the Part D sponsor may design its exception process so that Part D drugs on the specialty tier(s) are not eligible for tiering exception(s) to non-specialty tiers.

* * * * *

■ 86. Section 423.582 is amended by adding paragraphs (e) through (h) to read as follows:

§ 423.582 Request for a standard redetermination.

* * * * *

(e) *Dismissing a request.* A Part D plan sponsor may dismiss a redetermination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting a redetermination is not a proper party under § 423.580.

(2) When the Part D plan sponsor determines the party failed to make out a valid request for redetermination that substantially complies with paragraph (a) of this section.

(3) When the party fails to file the redetermination request within the proper filing time frame in accordance with paragraph (b) of this section.

(4) When the enrollee or the enrollee's representative files a request for redetermination, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) The enrollee's representative, if any, does not wish to pursue the request for coverage.

(5) When a party filing the redetermination request submits a timely written request for withdrawal of the request for a redetermination with the Part D plan sponsor.

(f) *Notice of dismissal.* The Part D plan sponsor must mail or otherwise transmit a written notice of the dismissal of the redetermination request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the Part D plan sponsor vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(g) *Vacating a dismissal.* If good cause is established, a Part D sponsor may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(h) *Effect of dismissal.* The dismissal of a request for redetermination is binding unless the enrollee or other party requests review by the IRE or the decision is vacated under paragraph (g) of this section.

■ 87. Section 423.584 is amended by adding paragraph (f) to read as follows:

§ 423.584 Expediting certain redeterminations.

* * * * *

(f) *Dismissing a request.* The Part D plan sponsor may dismiss an expedited redetermination in accordance with § 423.582.

■ 88. Section 423.590 is amended by adding paragraphs (i) and (j) to read as follows:

§ 423.590 Timeframes and responsibility for making redeterminations.

* * * * *

(i) *Automatic forwarding of redeterminations made under a drug management program.* If on redetermination the plan sponsor affirms, in whole or in part, its denial related to an at-risk determination under a drug management program in accordance with § 423.153(f), the Part D plan sponsor must forward the case to the IRE contracted with CMS by the expiration of the applicable adjudication timeframe under paragraph (a)(2), (b)(2), or (d)(1) of this section.

(j) *Requests for review of a dismissal by the independent entity.* If the Part D plan sponsor dismisses a request for a reconsideration in accordance with § 423.582(e) or § 423.584(f), the enrollee or other party has the right to request review of the dismissal by the independent entity. A request for review of a dismissal must be filed in writing with the independent entity within 60 calendar days from the date of the Part D plan sponsor's dismissal notice.

■ 89. Section 423.600 is amended by—

■ a. Revising paragraph (b); and

■ b. Adding paragraphs (f) through (k).

The revision and additions read as follows:

§ 423.600 Reconsideration by an independent review entity (IRE).

* * * * *

(b) When an enrollee, or an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee), files an appeal or a determination is forwarded to the IRE by a Part D plan sponsor, the IRE is required to solicit the views of the prescribing physician or other prescriber.

(1) The IRE may solicit the views of the prescribing physician or other prescriber orally or in writing.

(2) A written account of the prescribing physician's or other prescriber's views (prepared by either the prescribing physician, other prescriber, or IRE, as appropriate) must be contained in the IRE record.

* * * * *

(f) The party who files a request for reconsideration may withdraw it by filing a written request with the IRE.

(g) The independent entity may dismiss a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting a reconsideration is not a proper party under paragraph (a) of this section.

(2) When the IRE determines the party failed to make out a valid request for reconsideration that substantially complies with paragraph (a) of this section.

(3) When the party fails to file the reconsideration request within the

proper filing time frame in accordance with paragraph (a) of this section.

(4) When an enrollee or the enrollee's representative files a request for reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) The enrollee's representative, if any, does not wish to continue the appeal.

(5) When a party filing the reconsideration request submits a timely written request for withdrawal of the request for a reconsideration with the IRE.

(h) The IRE mails or otherwise transmits a written notice of the dismissal of the reconsideration request to the parties. The notice must state the all of the following:

(1) The reason for the dismissal.

(2) That there is a right to request that the IRE vacate the dismissal action.

(3) The right to a review of the dismissal in accordance with § 423.2004.

(i) If good cause is established, the IRE may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(j) An enrollee has a right to have an IRE's dismissal reconsidered in accordance with § 423.2004.

(k) If the IRE determines that the Part D plan sponsor's dismissal was in error, the IRE vacates the dismissal and remands the case to the Part D plan sponsor for reconsideration. The IRE's decision regarding an Part D plan sponsor's dismissal, including a decision to deny a request for review of a dismissal, is binding and not subject to further review.

■ 90. Section 423.760 is amended by—

■ a. Redesignating paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5); and

■ b. Adding a new paragraph (b)(3).

The addition reads as follows:

§ 423.760 Determinations regarding the amount of civil money penalties and assessments imposed by CMS.

* * * * *

(b) * * *

(3) CMS calculates the minimum penalty amounts under paragraphs (b)(1) and (2) of this section using the following criteria:

(i) *Definitions for calculating penalty amounts*—(A) *Per determination.* The penalty amounts calculated under paragraph (b)(1) of this section.

(B) *Per enrollee.* The penalty amounts calculated under paragraph (b)(2) of this section.

(C) *Standard minimum penalty.* The per enrollee or per determination amount that is dependent on the type of adverse impact that occurred.

(D) *Aggravating factor(s).* Specific penalty amounts that may increase the per enrollee or per determination standard minimum penalty and are determined based on criteria under paragraph (a) of this section.

(E) *Cost-of-living multiplier.* The percent change between each year's published October consumer price index for all urban consumers (United States city average), which is released by the Office of Management and Budget (OMB) annually.

(ii) *Calculation of penalty amounts.* (A) Per determination and per enrollee penalty amounts are increased by multiplying the current standard minimum penalty and aggravating factor amounts by the cost-of-living multiplier.

(B) The minimum penalty and aggravating factor amounts will be updated no more often than every 3 years.

(C) CMS tracks the calculation and accrual of the standard minimum penalty and aggravating factor amounts and announce them on an annual basis.

* * * * *

■ 91. Section 423.2006 is amended by redesignating paragraphs (c)(1) and (2) as paragraphs (c)(2) and (3) and adding a new paragraph (c)(1) to read as follows:

§ 423.2006 Amount in controversy required for an ALJ hearing and judicial review.

* * * * *

(c) * * *

(1) The amount remaining in controversy is computed as the projected value described in paragraph (c)(2) or (3) of this section, reduced by any cost sharing amounts, including deductible, coinsurance, or copayment amounts that may be collected from the enrollee for the Part D drug(s).

* * * * *

§ 423.2014 [Amended]

■ 92. Section 423.2014 is amended in paragraph (a)(1)(ii) by removing the phrase ''appointed representative'' and adding in its place the phrase ''representative''.

§ 423.2036 [Amended]

■ 93. Section 423.2036 is amended in paragraphs (c) and (d) by removing the phrase ''appointed representative'' and adding in its place the phrase ''representative'' each time it appears.

■ 94. Section 423.2260 is revised to read as follows:

§ 423.2260 Definitions.

The definitions in this section apply for this subpart unless the context indicates otherwise.

Advertisement (Ad) means a read, written, visual, oral, watched, or heard call to attention. Advertisements can be considered communication or marketing based on the intent and content of the message.

Alternate format means used to convey information to individuals with visual, speech, physical, hearing, and intellectual disabilities (for example, braille, large print, audio).

Banner means a type of advertisement feature typically used in television ads that is intended to be brief, and flashes limited information across a screen for the sole purpose of enticing a prospective enrollee to contact the MA plan (for example, obtain more information) or to alert the viewer that information is forthcoming.

Banner-like advertisement is an advertisement that uses a banner-like feature, that is typically found in some media other than television (for example, outdoors and on the internet).

Communications means activities and use of materials created or administered by the Part D sponsor or any downstream entity to provide information to current and prospective enrollees. Marketing is a subset of communications.

Marketing means communications materials and activities that meet both the following standards for intent and content:

(1) Intended to do any of the following:

(i) Draw a beneficiary's attention to a Part D plan or plans.

(ii) Influence a beneficiary's decision making process when making a Part D plan selection.

(iii) Influence a beneficiary's decision to stay enrolled in a Part D plan (that is, retention-based marketing).

(2) Include or address content regarding any of the following:

(i) The plan's benefits, benefits structure, premiums or cost sharing.

(ii) Measuring or ranking standards (for example, star ratings or plan comparisons).

(3) In evaluating the intent of an activity or material, CMS will consider objective information including, but not limited to, the audience of the activity or material, other information communicated by the activity or material, and timing and other context of the activity or material and is not limited to the MA organization's stated intent.

Outdoor advertising (ODA) means outdoor material intended to capture the

attention of a passing audience (for example, billboards, signs attached to transportation vehicles). ODA may be a communication or marketing material.

■ 95. Section 423.2261 is added to read as follows:

§ 423.2261 Submission, review, and distribution of materials.

(a) *General requirements.* MA organizations must submit all marketing materials, all election forms, and certain designated communications materials for CMS review.

(1) The Health Plan Management System (HPMS) is the primary system of record for the collection, review, and storage of materials that must be submitted for review.

(2) Materials must be submitted to the HPMS Marketing Module directly by the Part D sponsor. Third party and downstream entities are not permitted to submit materials directly to CMS.

(b) *CMS review of marketing materials and election forms.* Except as provided in paragraph (b) of this section, a Part D sponsor may not distribute or otherwise make available any marketing materials (as defined in § 423.2260) or election forms unless one of the following occurs:

(1) CMS has reviewed and approved the material.

(2) The material has been deemed approved; that is, CMS has not rendered a disposition for the material within 45 days (or 10 days if using CMS model or standardized marketing materials as outlined in § 422.2267(e) of this chapter) of submission to CMS. Materials that have been deemed may be used by the Part D sponsor.

(3) The material has been accepted under Files and Use, as follows:

(i) The MA organization may distribute certain types of marketing materials, designated by CMS based on the material's content, audience, and intended use, as they apply to potential risk to the beneficiary, 5 days following the submission.

(ii) The Part D sponsor must certify that the material meets all applicable CMS communications and marketing requirements in §§ 423.2260 through 423.2267.

(c) *CMS review of communications materials.* CMS does not generally require submission and approval of communications materials prior to use, with the exception of certain designated communications that are critical to the beneficiary understanding or accessing their benefits (for example, the Evidence of Coverage (EOC)).

(d) *Standards for CMS review.* CMS reviews materials to ensure the following:

(1) Compliance with all applicable requirements under §§ 423.2260 through 423.2267.

(2) Benefit and cost information is an accurate reflection of what is contained in the Part D sponsor's bid.

(3) CMS may determine, upon review of such materials, that the materials must be modified, or may no longer be used.

■ 96. Section 423.2262 is revised to read as follows:

§ 423.2262 General communications materials and activity requirements.

Part D sponsors may not mislead, confuse, or provide inaccurate information to current or potential enrollees.

(a) *General rules.* Part D sponsors must ensure their statements and the terminology used in communications activities and materials adhere to the following requirements:

(1) Part D sponsors may not do any of the following:

(i) Provide information that is inaccurate or misleading.

(ii) Make unsubstantiated statements, including superlatives or pejoratives.

(iii) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor.

(iv) Engage in any discriminatory activity such as attempting to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas, or vice versa.

(v) Target potential enrollees based on higher or lower income levels.

(vi) Target potential enrollees based on health status.

(vii) State or imply plans are only available to seniors rather than to all Medicare beneficiaries.

(viii) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.

(ix) Display the names or logos or both of co-branded network pharmacies on the sponsor's member identification card, unless the pharmacy names or logos or both are related to the member selection of specific pharmacies.

(x) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name, for example, ''Super Medicare Drug Plan (PDP)''.

(xi) Claim they are recommended or endorsed by CMS, Medicare, or the HHS.

(xii) Convey that a failure to pay premium will not result in disenrollment.

(xiii) Use the term ''free'' to describe a $0 premium, any type of reduction in premium, reduction in deductibles or cost sharing, low-income subsidy, or cost sharing for dual eligible individuals.

(xiv) State or imply a plan is available only to or is designed for Medicaid beneficiaries.

(xv) Market a Part D plan not designed to serve dual eligible beneficiaries as if it were a plan designed to serve dual eligible beneficiaries.

(xvi) Target marketing efforts primarily to dual eligible individuals.

(xvii) Claim a relationship with the state Medicaid agency, unless a contract to coordinate Medicaid services for that plan is in place.

(2) Part D sponsors may do the following:

(i) State that the Part D sponsor is approved to participate in Medicare programs or is contracted to administer Medicare benefits or both.

(ii) Use the term ''Medicare-approved'' to describe benefits or services in materials or both.

(b) *Product endorsements and testimonials.* (1) Product endorsements and testimonials may take any of the following forms:

(i) Television or video ads.

(ii) Radio ads.

(iii) Print ads.

(iv) Social media ads. In cases of social media, the use of a previous post, whether or not associated with or originated by the Part D sponsor, is considered a product endorsement or testimonial.

(v) Other types of ads.

(2) Part D sponsors may use individuals to endorse the Part D sponsor's product provided the endorsement or testimonial adheres to the following requirements:

(i) The speaker must identify the Part D sponsor's product or company by name.

(ii) Medicare beneficiaries endorsing or promoting the Part D sponsor must have been an enrollee at the time the endorsement or testimonial was created.

(iii) The endorsement or testimonial must clearly state that the individual was paid for the endorsement or testimonial, if applicable.

(iv) If an individual is used (for example, an actor) to portray a real or fictitious situation, the advertisement must state that it is an actor portrayal.

(c) *Requirements when including certain telephone numbers in materials.* (1) Part D sponsors must adhere to the following requirements for including certain telephone numbers in materials:

(i) When a Part D sponsor includes its customer service number, the hours of operation must be included the first time (at a minimum) the number appears.

(ii) When a Part D sponsor includes its customer service number, it must provide a toll-free TTY number in conjunction with the customer service number in the same font size.

(iii) On every material where 1–800–MEDICARE or Medicare TTY appears, the Part D sponsor must include the hours and days of operation for 1–800–MEDICARE (that is, 24 hours a day/7 days a week).

(2) The following advertisement types are exempt from these requirements:

(i) Outdoor advertising.

(ii) Banners or banner-like ads.

(iii) Radio advertisements and sponsorships.

(d) *Standardized material identification (SMID).* (1) Part D sponsors must use a standardized method of identification for oversight and tracking of materials beneficiaries receive.

(2) The SMID consists of the following three parts:

(i) The Part D sponsor's contract or Multi-Contract Entity (MCE) number, (that is, ''S'' for PDPs, or ''Y'' for MCE identifier) followed by an underscore, except that the SMID for multi-plan marketing materials must begin with the word ''MULTI–PLAN'' instead of the Part D sponsor's contract number (for example, S1234_abc123_C or MULTI–PLAN_efg456_M).

(ii) A series of alpha numeric characters (at the Part D sponsor's discretion) unique to the material followed by an underscore.

(iii) An uppercase ''C'' for communication materials or an uppercase ''M'' for marketing materials (for example, S1234_abc123_C or S5678_efg456_M).

(3) The SMID is required on all materials except the following:

(i) Membership ID card.

(ii) Envelopes, radio ads, outdoor advertisements, banners, banner-like ads, and social media comments and posts.

(iii) OMB-approved forms/documents, except those materials included in § 423.2267.

(iv) Corporate notices or forms (that is, not Part D-specific) meeting the definition of communications such as privacy notices and authorization to disclose protected health information (PHI).

(v) Agent-developed communications materials that are not marketing.

(4) Non-English and alternate format materials, based on previously created materials, may have the same SMID as the material on which they are based.

■ 97. Section 423.2263 is added to read as follows.

§ 423.2263 General marketing requirements.

Marketing is a subset of communications and therefore must follow the requirements outlined in § 423.2262 as well as this section. Marketing (as defined in § 423.2260) must additionally meet the following requirements:

(a) Part D sponsors may begin marketing prospective plan year offerings on October 1 of each year for the following contract year. Part D sponsors may market the current and prospective year simultaneously provided materials clearly indicate what year is being discussed.

(b) In marketing, Part D sponsors may not do any of the following:

(1) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.

(2) Offer gifts to potential enrollees, unless the gifts are of nominal value (as governed by guidance published by the Department of Health and Human Services Office of Inspector General (HHS OIG)), are offered to all potential enrollees without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

(3) Provide meals to potential enrollees regardless of value.

(4) Market non-health care related products to prospective enrollees during any Part D sales activity or presentation. This is considered cross-selling and is prohibited.

(5) Compare their plan to other plans, unless the information is accurate, not misleading, and can be supported by the Part D sponsor making the comparison.

(6) Display the names or logos or both of pharmacy co-branding partners on marketing materials, unless the materials clearly indicate via a disclaimer or in the body that ''Other pharmacies are available in the network.''

(7) Knowingly target or send unsolicited marketing materials to any Part D enrollee during the Open Enrollment Period (OEP).

(i) During the OEP, Plans/Part D sponsors may do any of the following:

(A) Conduct marketing activities that focus on other enrollment opportunities, including but not limited to marketing to age-ins (who have not yet made an enrollment decision), marketing by 5-star plans regarding their continuous enrollment special election period (SEP), and marketing to dual-eligible and LIS beneficiaries who, in general, may make changes once per calendar quarter during the first nine months of the year.

(B) Send marketing materials when a beneficiary makes a proactive request;

(C) At the beneficiary's request, have one-on-one meetings with a sales agent; and

(D) At the beneficiary's request, provide information on the OEP through the call center.

(ii) During the OEP, Plans/Part D sponsors may not:

(A) Send unsolicited materials advertising the ability/opportunity to make an additional enrollment change or referencing the OEP;

(B) Specifically target beneficiaries who are in the OEP because they made a choice during Annual Enrollment Period (AEP) by purchase of mailing lists or other means of identification;

(C) Engage in or promote agent/broker activities that intend to target the OEP as an opportunity to make further sales; or

(D) Call or otherwise contact former enrollees who have selected a new plan during the AEP.

(c) The following requirements apply to how Part D sponsors must display CMS issued Star Ratings:

(1) References to individual Star Rating measure(s) must also include references to the contract's overall Star Rating.

(2) May not use an individual underlying category or measure to imply overall high Star Ratings.

(3) Must be clear that the rating is out of 5 stars.

(4) Must clearly identify the Star Rating contract year.

(5) May only market the Star Ratings in the service area in which the Star Rating is applicable.

(6) The following requirements apply to all 5 Star PDP contracts:

(i) May not market the 5 star special enrollment period, as defined in § 423.38(c)(20), after November 30 of each year if the contract has not received an overall 5 star for the next contract year.

(ii) May use CMS' 5 star icon or may create their own icon.

(7) The following requirements apply to all Low Performing MA contracts:

(i) The Low Performing Icon must be included on all materials about or referencing the specific contract's Star Ratings.

(ii) Must state the Low Performing Icon means that the Part D sponsor's contract received a summary rating of 2.5 stars or below in Part D for the last 3 years.

(iii) May not attempt to refute or minimize Low Performing Status.

■ 98. Section 423.2264 is revised to read as follows:

§ 423.2264 Beneficiary contact.

For the purpose of this section, beneficiary contact applies to all outreach activities to a beneficiary or their caregivers by the Part D sponsor or its agents and brokers.

(a) *Unsolicited contact.* Subject to the rules for contact for plan business in paragraph (b) of this section, the following rules apply when materials or activities are given or supplied to a beneficiary or their caregiver without prior request:

(1) Part D sponsors may make unsolicited direct contact by conventional mail and other print media (for example, advertisements and direct mail) or email (provided every email contains an opt-out option).

(2) Part D sponsors may not do any of the following:

(i) Use door to door solicitation, including leaving information of any kind, except that information may be left when an appointment is pre-scheduled but the beneficiary is not home.

(ii) Approach enrollees in common areas such as parking lots, hallways, lobbies.

(iii) Send unsolicited direct messages from social media platforms.

(iv) Use telephone solicitation (that is, cold calling), text messages, or voicemail messages, including, but not limited to the following:

(A) Unsolicited calls based on referrals.

(B) Calls to former enrollees who have disenrolled or those in the process of disenrolling, except to conduct disenrollment surveys for quality improvement purposes.

(C) Calls to beneficiaries who attended a sales event, unless the beneficiary gave express permission to be contacted.

(D) Unsolicited calls to prospective enrollees to confirm receipt of mailed information.

(3) Calls are not considered unsolicited if the beneficiary provides consent or initiates contact with the plan. For example, returning phone calls or calling an individual who has completed a business reply card requesting contact is not considered unsolicited.

(4) Part D sponsors are responsible to ensure sales staff, including agents and brokers, abide by Federal and state laws related to consumer protection, including but not limited to do not call list requirements.

(b) *Contact for plan business.* Part D sponsors may contact current, and to a more limited extent, former members, including those enrolled in other products offered by the parent organization, to discuss plan business, in accordance with the following requirements:

(1) A Part D sponsor may conduct the following activities as plan business:

(i) Call current enrollees, including those in non-Medicare products, to discuss Medicare products. Examples of such calls include, but are not limited to the following:

(A) Enrollees aging into Medicare from commercial products.

(B) Existing enrollees, including Medicaid enrollees, to discuss other Medicare products or plan benefits.

(C) Members in an MA or cost plan to discuss other Medicare products.

(ii) Call beneficiaries who submit enrollment applications to conduct business related to enrollment.

(iii) With prior CMS approval, call LIS enrollees that a plan is prospectively losing to due reassignment. CMS decisions to approve calls are for limited circumstances based on the following:

(A) The proximity of cost of the losing plan as compared to the national benchmark, and

(B) The selection of plans in the service area that are below the benchmark.

(iv) Agents/brokers calling clients who are enrolled in other products they may sell, such as automotive or home insurance.

(v) Part D sponsors may not make unsolicited calls about other lines of business as a means of generating leads for Medicare plans.

(2) [Reserved]

(c) *Events with beneficiaries.* Part D sponsors and their agent/brokers may hold educational events, marketing or sales events, and personal marketing appointments to meet with Medicare beneficiaries, either face-to-face or virtually. The requirements for each type of event are as follows:

(1) Educational events must be advertised as such and be designed to generally inform beneficiaries about Medicare, including Medicare Advantage, Prescription Drug programs, or any other Medicare program.

(i) At educational events, Part D sponsors and agents/brokers may not market specific Part D sponsors or benefits.

(ii) Part D sponsors holding or participating in educational events may do any of the following:

(A) Distribute communication materials.

(B) Answer beneficiary initiated questions pertaining to Part D sponsors.

(C) Set up future personal marketing appointments.

(D) Distribute business cards.

(E) Obtain beneficiary contact information, including Scope of Appointment forms.

(iii) Part D sponsors holding or participating in educational events may not conduct sales or marketing presentations or distribute or accept plan applications.

(2) Marketing or sales events are group events that fall within the definition of marketing at § 423.2260.

(i) If a marketing event directly follows an educational event, the Part D sponsor or agent/broker must provide an opportunity for beneficiaries to determine if they want to continue with the marketing event.

(ii) Part D sponsors holding or participating in marketing events may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Collect Scope of Appointment forms for future personal marketing appointments.

(D) Conduct marketing presentations.

(iii) Part D sponsors holding or participating in marketing events may not do any of the following:

(A) Require sign in sheets or require attendees to provide contact information as a prerequisite for attending an event.

(B) Conduct activities, including health screenings, health surveys, or other activities that are used for or could be viewed as being used to target a subset of members (that is ''cherry-picking'').

(C) Use information collected for raffles or drawings for any purpose other than raffles or drawings.

(3) Personal marketing appointments are those appointments that are tailored to an individual or small group (for example, a married couple). Personal marketing appointments are not defined by the location.

(i) Prior to the personal marketing appointment beginning, the Part D sponsor (or the agent/broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies).

(ii) Part D sponsors holding a personal marketing appointment may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Conduct marketing presentations.

(D) Review the individual needs of the beneficiary including, but not limited to, health care needs and history, commonly used medications, and financial concerns.

(iii) Part D sponsors holding a personal marketing appointment may not do any of the following:

(A) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

(B) Market additional health related lines of plan business not identified prior to an individual appointment without a separate scope of appointment identifying the additional lines of business to be discussed.

(C) Market non-health related products such as annuities.

■ 99. Section 423.2265 is added to read as follows:

§ 423.2265 Websites.

As required under § 423.128(d)(2), Part D sponsors must have a website.

(a) *General website requirements.* (1) Part D sponsor websites must meet the all of the following requirements:

(i) Maintain current year contract content through December 31 of each year.

(ii) Notify users when they will leave the Part D sponsor's Medicare site.

(iii) Include or provide access to (for example, through a hyperlink) applicable disclaimers with corresponding content. Overarching disclaimers, such as the Federal Contracting Statement, are not required on every page.

(iv) Be updated to reflect the most current information within 30 days of any information on the website changing.

(v) Keep PDP content separate and distinct from other lines of business, including Medicare Supplemental Plans.

(2) Part D sponsor websites may not do any of the following:

(i) Require beneficiaries to enter any information other than zip code, county, or state for access to non-beneficiary-specific website content.

(ii) Provide links to foreign drug sales, including advertising links.

(iii) State that the Part D sponsor is not responsible for the content of their social media pages or the website of any first tier, downstream, or related entity that provides information on behalf of the Part D sponsor.

(b) *Required content.* A Part D sponsor's websites must include the following content:

(1) A toll-free customer service number, TTY number, and days and hours of operation.

(2) A physical or Post Office Box address.

(3) A PDF or copy of a printable pharmacy directory.

(4) A searchable pharmacy directory.

(5) A searchable formulary.

(6) Information on enrollees' and Part D sponsors' rights and responsibilities upon disenrollment. Part D sponsors may either post this information or provide specific information on where it is located in the Evidence of Coverage together with a link to that document.

(7) A description of and information on how to file a grievance, organizational determination, and appeal.

(8) Prominently display a link to the *Medicare.gov* electronic complaint.

(9) Privacy Notice under the HIPAA Privacy Rule (45 CFR part 160).

(10) Prescription Drug Transition Policy.

(11) LIS Premium Summary Chart.

(12) Prescription Drug Transition Policy.

(c) *Required posted materials.* A Part D sponsor's website must provide access to the following materials, in a printable format, within the timeframes noted in paragraphs (c)(1) and (2) of this section.

(1) The following documents for each plan year must be posted on the website by October 15 prior to the beginning of the plan year:

(i) Evidence of Coverage.

(ii) Annual Notice of Change (for renewing plans).

(iii) Summary of Benefits.

(iv) Pharmacy Directory.

(v) Formulary.

(vi) Utilization Management Forms for physicians and enrollees.

(2) The following documents must post on the website throughout the year and be updated as required:

(i) Prior Authorization Forms for Physicians and Enrollees.

(ii) Part D Model Coverage Determination and Redetermination Request Forms.

(iii) Exception request forms for physicians (which must be posted by January 1 for new plans).

(iv) CMS Star Ratings document, which must be posted within 21 days after its release on the Medicare Plan Finder.

■ 100. Section 423.2266 is added to read as follows:

§ 423.2266 Activities with healthcare providers or in the healthcare setting.

(a) *Where marketing is prohibited.* The requirements in paragraphs (c) through (e) of this section apply to activities in the health care setting. Marketing activities and materials are not permitted in areas where care is being administered, including but not limited to the following:

(1) Exam rooms.

(2) Hospital patient rooms.

(3) Treatment areas where patients interact with a provider and his/her clinical team and receive treatment (including dialysis treatment facilities).

(4) Pharmacy counter areas.

(b) *Where marketing is permitted.* Marketing activities and materials are permitted in common areas within the health care setting, including, not limited to, the following:

(1) Common entryways.

(2) Vestibules.

(3) Waiting rooms.

(4) Hospital or nursing home cafeterias.

(5) Community, recreational, or conference rooms.

(c) *Provider-initiated activities.* Provider-initiated activities are activities conducted by a provider at the request of the patient, or as a matter of a course of treatment, and occur when meeting with the patient as part of the professional relationship between the provider and patient. Provider-initiated activities do not include activities conducted at the request of the Part D sponsor or pursuant to the network participation agreement between the Part D sponsor and the provider. Provider-initiated activities that meet this definition fall outside of the definition of marketing in § 423.2260. Permissible provider-initiated activities include:

(1) Distributing unaltered, printed materials created by CMS, such as reports from Medicare Plan Finder, the ''Medicare & You'' handbook, or ''Medicare Options Compare'' (from *https://www.medicare.gov*) including in areas where care is delivered.

(2) Providing the names of Part D sponsors with which they contract.

(3) Answering questions or discussing the merits of a Part D plan or plans, including cost sharing and benefit information including in areas where care is delivered.

(4) Referring patients to other sources of information, such as State Health Insurance Assistance Program (SHIP) representatives, plan marketing representatives, State Medicaid Office, local Social Security Offices, CMS' website at *https://www.medicare.gov,* or 1–800–MEDICARE.

(5) Referring patients to Part D marketing materials available in common areas.

(6) Providing information and assistance in applying for the LIS.

(7) Announcing new or continuing affiliations with Part D sponsors, once a contractual agreement is signed. Announcements may be made through any means of distribution.

(d) *Plan-initiated provider activities.* Plan-initiated provider activities are those activities conducted by a provider at the request of a Part D sponsor.

During a plan-initiated provider activity, the provider is acting on behalf of the Part D sponsor. For the purpose of plan-initiated activities, the Part D sponsor is responsible for compliance with all applicable regulatory requirements.

(1) During plan-initiated provider activities, Part D sponsors must ensure that the provider does not:

(i) Accept/collect scope of appointment forms.

(ii) Accept Medicare enrollment applications.

(iii) Make phone calls or direct, urge, or attempt to persuade their patients to enroll in a specific plan based on financial or any other interests of the provider.

(iv) Mail marketing materials on behalf of a Part D sponsor.

(v) Offer inducements to persuade patients to enroll with a particular Part D sponsor.

(vi) Conduct health screenings as a marketing activity.

(vii) Distribute marketing materials or enrollment forms in areas where care is being delivered.

(viii) Offer anything of value to induce enrollees to select the provider.

(ix) Accept compensation from the Part D sponsor for any marketing or enrollment activities.

(2) During plan-initiated provider activities, the provider may do any of the following:

(i) Make available, distribute, and display communications materials, including in areas where care is being delivered.

(ii) Provide or make available marketing materials and enrollment forms in common areas.

(e) *Part D sponsor activities in the healthcare setting.* Part D sponsor activities in the health care setting are those activities, including marketing activities, that are conducted by Part D sponsor or any downstream entity, but not by a provider. All marketing must follow the requirements in paragraphs (a) and (b) of this section. However, during Part D sponsor activities, the following is permitted:

(1) Accepting and collect Scope of Appointment forms.

(2) Accepting enrollment forms.

(3) Making available, distributing, and displaying communications materials, including in areas where care is being delivered.

■ 101. Section 423.2267 is added to read as follows:

§ 423.2267 Required materials and content.

For information CMS deems to be vital to the beneficiary, including information related to enrollment, benefits, health, and rights, the agency may develop materials or content that are either standardized or provided in a model form. Such materials and content are collectively referred to as required.

(a) *Standards for required materials and content.* All required materials and content, regardless of categorization as standardized in paragraph (b) of this section or model in paragraph (c) of this section, must meet the following:

(1) Be in a 12pt font (Times New Roman or equivalent).

(2) For markets with a significant non-English speaking population, be in the language of these individuals. Part D sponsors must translate required materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

(3) Be provided to the beneficiary within CMS's specified timeframes.

(b) *Standardized materials.* Standardized materials and content are required materials and content that must be used in the form and manner provided by CMS.

(1) When CMS issues standardized material or content, a Part D sponsor must use the document without alteration except for the following:

(i) Populating variable fields.

(ii) Correcting grammatical errors.

(iii) Adding customer service phone numbers.

(iv) Adding plan name, logo, or both.

(v) Deleting content that does not pertain to the plan type (for example, removing Part D language for a MA-only plan).

(vi) Adding the SMID.

(vii) Adding the Privacy Notice under the HIPAA Privacy Rule.

(2) When CMS issues standardized content, Part D sponsors—

(i) Must use the language provided without alteration.

(ii) May develop accompanying language for standardized material or content, provided it does not conflict with the standardized material or content. For example, CMS may issue standardized content associated with an appeal notification. Part D sponsors may draft a letter that includes the standardized content in the body of the letter. The remaining language in the letter is at the plan's discretion, provided it does not conflict with the standardized content.

(c) *Model materials.* Model materials and content are those required materials and content created by CMS as an example of how to convey beneficiary information. When drafting required materials or content based on CMS models, MA organizations—

(1) Must accurately convey the vital information in the required material or content to the beneficiary, although the Part D sponsor is not required to use CMS model materials or content verbatim; and

(2) Must follow CMS's specified order of content, when specified.

(d) *Delivery of required materials.* Part D sponsor must mail required materials in hard copy or provide them electronically, following the requirements in paragraphs (d)(1) and (2) of this section.

(1) For hard copy mailed materials, each enrollee must receive his or her own copy, except in cases of non-beneficiary-specific material(s) where the Part D sponsor has determined multiple enrollees are living in the same household and it has reason to believe the enrollees are related. In that case, the Part D sponsor may mail one copy to the household. The Part D sponsor must provide all enrollees an opt-out process so the enrollees can each receive his or her own copy, instead of a copy to the household. Materials specific to an individual beneficiary must always be mailed to that individual.

(2) Materials may be delivered electronically following the requirements in paragraphs (d)(2)(i) and (ii) of this section.

(i) Without prior authorization, Part D sponsor may mail new and current enrollees a notice informing enrollees how to electronically access the following required materials: The Evidence of Coverage, Provider and Pharmacy Directories, and Formulary. The following requirements apply:

(A) The Part D sponsor may mail one notice for all materials or multiple notices.

(B) Notices for prospective year documents may not be mailed prior to September 1 of each year, but must be sent in time for an enrollee to access the specified documents by October 15 of each year.

(C) The Part D sponsor may send the notice throughout the year to new enrollees.

(D) The notice must include the website address to access the documents, the date the documents will be available if not currently available, and a phone number to request that hard copy documents be mailed.

(E) The notice must provide the enrollee with the option to request hardcopy materials. Requests may be materials specific, and must have the option of a one-time request or a permanent request that must stay in place until the enrollee chooses to receive electronic materials again.

(F) Hard copies of requested materials must be sent within three business days.

(ii) With prior authorization from the enrollee, the Part D sponsor may provide any required material or content electronically. To do so, the Part D sponsor must do all of the following:

(A) Obtain prior consent from the enrollee. The consent must specify both the media type and the specific materials being provided in that media type.

(B) Provide instructions on how and when enrollees can access the materials.

(C) Have a process through which an enrollee can request hard copies be mailed, providing the beneficiary with the option of a one-time request or a permanent request (which must stay in place until the enrollee chooses to receive electronic materials again), and with the option of requesting hard copies for all or a subset of materials. Hard copies must be mailed within 3 business days.

(D) Have a process for automatic mailing of hard copies when electronic versions or the chosen media type is undeliverable.

(e) *CMS required materials and content.* The following are required materials that must be provided to current and or perspective enrollees, as applicable, in the form and manor outlined in this section:

(1) *Evidence of Coverage (EOC).* The EOC is a standardized communications material through which certain required information (under § 423.128(b)) must be provided annually.

(i) Must be provided to current enrollees of plan by October 15 of each Year.

(ii) Must be provided to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(2) *Annual Notice of Change (ANOC).* The ANOC is a standardized marketing material through which plans must provide the information required under § 423.128(g)(2) annually.

(i) Must send for enrollee receipt no later than September 30 of each year.

(ii) Enrollees with an October 1, November 1, and December 1 effective date must receive within ten (10) calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(3) *Pre-Enrollment Checklist (PECL).* The PECL is a standardized communications material that plans must provide to prospective enrollees with the enrollment form and Summary of Benefits (SB) so that the enrollees understand important plan benefits and rules. The PECL references information on the following:

(i) The EOC.

(ii) Provider directory.

(iii) Pharmacy directory.

(iv) Formulary.

(v) Premiums/copayments/coinsurance.

(vi) Emergency/urgent coverage.

(vii) Plan-type rules.

(4) *Summary of Benefits (SB).* Part D sponsors must disseminate a summary of highly utilized coverage that include benefits and cost sharing to prospective Medicare beneficiaries, known as the SB. The SB is a model marketing material. It must be in a clear and accurate format.

(i) The SB must be provided with an enrollment form that meets the following:

(A) In hardcopy with a paper enrollment form.

(B) For online enrollment, the SB must be made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where they can access the SB.

(ii) The SB must include the following information:

(A) The prescription drug expense (tiers/levels) as follows:

(*1*) Deductible, the initial coverage phase, coverage gap, and catastrophic coverage.

(*2*) A note that costs may differ based on pharmacy type or status (for example, preferred/non-preferred, mail order, long-term care (LTC) or home infusion, and 30- or 90-day supply), when applicable.

(*3*) For dual eligible enrollees with differing levels of cost must state how cost sharing and benefits differ depending on the level of Medicaid eligibility.

(B) The SB may include other health related benefits.

(5) *Enrollment/Election form.* This is the model communications material through which plans must provide the information required under § 423.32(b).

(6) *Enrollment Notice.* This is a model communications material through which plans must provide the information required under § 423.32(d).

(7) *Disenrollment Notice.* This is a model communications material through which plans must provide the information required under § 423.36(b)(2).

(8) *Formulary.* This is a model communications material through which Part D sponsors must provide information required under § 423.128(b)(4).

(i) Must be provided to current enrollees of plan by October 15 of each year.

(ii) Must also provide to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(9) *Low Income Subsidy (LIS) Notice.* This is a model communications content through which Part D sponsors must notify potential enrollees of what their plan premium will be once they are eligible for Extra Help and receive the low-income subsidy.

(10) *Low Income Subsidy (LIS) Rider.* This is a model communications material provided to all enrollees who qualify for Extra Help. In the LIS Rider, the Part D sponsors must convey how much help the beneficiary will receive in the benefit year toward their Part D premium, deductible, and copayments provide to all beneficiaries who qualify for Extra Help.

(i) The LIS Rider must be provided at least once per year by September 30.

(ii) The LIS Rider must be sent to enrollees who qualify for Extra Help or have a change in LIS levels within 30 days of receiving notification from CMS.

(11) *Midyear Change Notification.* This is a model communications material through which plans must provide a notice to enrollees when there is a midyear change in benefits or plan rules, under the following timelines:

(i) Notices of changes in plan rules, unless otherwise addressed elsewhere in the regulation, must be provided 30 days in advance.

(ii) National Coverage Determination (NCD) changes announced or finalized less than 30 days before effective date, a notification is required as soon as possible.

(iii) Midyear NCD or legislative changes must be provided no later than 30 days after the NCD is announced.

(A) Plans may include the change in next plan mass mailing (for example, newsletter), provided it is within 30 days.

(B) The notice must also appear on the MA organization's website.

(12) *Non-renewal Notice.* This is a model communications material through which plans must provide the information required under § 423.507.

(i) The Non-renewal Notice must be provided at least 90 calendar days before the date on which the nonrenewal is effective. For contracts ending on December 31, the notice must be dated October 2 to ensure national consistency in the application of Medigap Guaranteed Issue (GI) rights to all enrollees, except for those enrollees

in Medicare-Medicaid Plans (MMPs) and special needs plans (SNPs).

(ii) The Non-renewal Notice must do all of the following:

(A) Inform the enrollee that their plan will no longer be offered and told when their plan will end.

(B) Identify the last day the enrollee has to make a Part D sponsor selection. Include any applicable open enrollment periods or special election periods or both (for example, Medicare open enrollment, non-renewal special election period).

(C) Explain what they must do to continue receiving Medicare coverage and what will happen if the enrollee chooses to do nothing.

(D) Include all available health plan options must be included in the enrollee's notice along with an explanation of how to obtain each option.

(E) Specify when coverage will start after a new Medicare plan is chosen.

(F) List 1–800–MEDICARE contact information together with other organizations that may be able to assist with comparing plans (for example, SHIPs).

(H) Include the Part D sponsor's organization's telephone number, TTY number, and hours and days of operation.

(13) *Part D Transition Letter.* This is a model communications material that must be provided to the beneficiary when they receive a transition fill for a nonformulary drug. The Part D Transition Letter must be sent within 3 days of adjudication of temporary transition fill.

(14) *Pharmacy Directory.* This is a model communications material through which Part D sponsors must provide the information required under § 423.128. The pharmacy directory must meet all of the following:

(i) Be provided to current enrollees by October 15 of each year and upon request, within 3 business days of the request.

(ii) Be provided to new enrollees within 10 calendars days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(iii) Plan sponsors must update directory information any time the Part D sponsor becomes aware of changes.

(A) All updates to the online provider directories are expected to be completed within 30 days of receiving information requiring update.

(B)(*1*) Updates to hardcopy provider directories must be completed within 30 days.

(*2*) Hardcopy directories that include separate updates via addenda are considered up-to-date.

(15) *Prescription transfer letter.* This is a model communications material must be sent when a Part D sponsor requests permission from an enrollee to fill a prescription at a different network pharmacy than the one currently being used by enrollee.

(16) *Star Ratings Document.* This is a standardized marketing material through which Star Ratings information is conveyed to prospective enrollees.

(i) The Star Ratings Document is generated through HPMS.

(ii) The Star Ratings Document must be provided with an enrollment form as follows:

(A) In hardcopy with a paper enrollment form.

(B) For online enrollment, made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where they can access the Star Ratings Document.

(iii) New Part D sponsor that have no Star Ratings are not required to provide the Star Ratings Document until the following contract year.

(iv) Updated Star Ratings must be used within 21 calendar days of release of updated information on Medicare Plan Finder.

(v) Updated Star Ratings must not be used until CMS releases Star Ratings on Medicare Plan Finder.

(17) *Coverage Determination Notices.* This is a model communications material through which plans must provide the information under § 423.568.

(18) *Excluded Provider Notices.* This is a model communications material through which plans must notify members when a provider they use has been excluded from participating in the Medicare program based on an OIG exclusion or the CMS preclusion list.

(19) *Notice of Denial of Medicare Prescription Drug Coverage.* This is a standardized material used to convey detailed descriptions of denied drug coverage and appeal rights.

(20) *Medicare Prescription Drug Coverage and Your Rights.* This is a standardized material used to convey a beneficiary's appeal rights when a drug cannot be filled at point-of-sale.

(21) *Medicare Part D Coverage Determination Request Form.* This is a model material used to collect additional information from a prescriber.

(22) *Request for Additional Information.* This is a standardized material used by the Part D sponsor to request a beneficiary obtain additional information from the prescriber regarding a beneficiary's exception request.

(23) *Notice of Right to an Expedited Grievance.* This is a model communications material used to convey a Medicare beneficiary's rights to request that a decision be made on a grievance or appeal within a shorter timeframe.

(24) *Notice of Inquiry.* This is a model communication from a prescription drug plan informing a beneficiary if a drug is covered by the formulary.

(25) *Notice of Case Status.* This is a model communications material used to inform a beneficiary of the denial of an appeal and additional appeal rights.

(26) *Request for Reconsideration of Medicare Prescription Drug Denial.* This is a model notice used to inform the beneficiary of rights to an independent review of a Part D sponsor's decision.

(27) *Notice of Redetermination.* This is a model communications material used to convey instructions for requesting an appeal of an adverse coverage determination.

(28) *Part D LEP Reconsideration Notice.* This is a model communication used to convey detailed instructions on how to request a reconsideration of an assessed Part D late enrollment penalty.

(29) *LEP Reconsideration Request Form.* This is a model communication used to request an appeal of a decision on an LEP by the independent review entity.

(30) *Request for Administrative Law Judge (ALJ) Hearing or Review of Dismissal.* This is a model communication used by an enrollee to request a hearing by the ALJ or a review of the IRE dismissal.

(31) *Appointment of Representative (AOR).* This is a standardized material used to assign an individual to act on behalf of a beneficiary for the purpose of an appeal, grievance, or coverage determination.

(32) *Federal Contracting Statement.* This is model content through which plans must convey that they have a contract with Medicare and that enrollment in the plan depends on contract renewal.

(i) The Federal Contracting Statement must include all of the following:

(A) Legal or marketing name of the organization.

(B) Type of plan (for example PDP).

(C) A statement that the organization has a contract with Medicare (when applicable, Part D sponsors may incorporate a statement that the organization has a contract with the State/Medicaid program).

(D) A statement that enrollment depends on contract renewal.

(ii) Part D sponsors must include the Federal Contracting Statement on all

marketing materials with the exception of the following:

(A) Banner and banner-like advertisements.

(B) Outdoor advertisements.

(C) Text messages.

(D) Social media.

(33) *Star Ratings Disclaimer.* This is standardized content. The disclaimer consists of the statement ''Every year, Medicare evaluates plans based on a 5-star rating system,'' and must be present whenever Star Ratings are mentioned in marketing materials, with the exception of when Star Ratings are published on small objects (that is, a give-away items such as a pens or rulers).

(34) *Availability of Non-English Translations Disclaimer.* This is standardized content. The disclaimer consists of the statement ''ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1–XXX–XXX–XXXX (TTY: 1–XXX–XXX–XXXX).''

(i) The disclaimer must be placed in non-English languages that meet the 5 percent threshold for language translation under paragraph (a)(2) of this section.

(ii) The disclaimer must be added to all required materials in this section.

(35) *Accommodations Disclaimer.* This is standardized content. The disclaimer consists of the statement ''For accommodations of persons with special needs at meetings call <phone and TTY number>'' and must be present on all advertisements and invitations to all events as described under § 423.2264(b).

(36) *Mailing Statements.* This is standardized content. It consists of statements on envelopes that Part D sponsor must include when mailing information to current members, as follows:

(i) Part D sponsors must include the following statement when mailing information about the enrollee's current plan: ''Required on all advertisements and invitations to events (educational and marketing).''

(ii) Part D sponsors must include the following statement when mailing health and wellness information ''Health and wellness or prevention information.''

(iii) The Part D sponsor must include the plan name; however, if the plan name is elsewhere on the envelope, the plan name does not need to be repeated in the disclaimer.

(iv) Delegated or sub-contracted entities and downstream entities that conduct mailings on behalf of a multiple Part D sponsors must also comply with this requirement, however, they do not have to include a plan name.

(37) *Promotional Give-Away Disclaimer.* This is model content. The disclaimer consists of a statement that must make clear that there is no obligation to enroll in a plan, and must be included when offering a promotional give-away such as a drawing, prizes, or a free gift.

(38) *Provider Co-branded Material Disclaimer.* This is standardized content. The disclaimer consists of the statement: ''Other Pharmacies/Physicians/Providers are available in our network,'' and must be included on materials that identify co-branding relationships with network provider or pharmacies.

§ 423.2268 [Removed]

■ 102 Section 423.2268 is removed.

■ 103. Section 423.2274 is revised to read as follows:

§ 423.2274 Agent, broker, and other third party requirements.

If a Part D sponsor uses agents and brokers to sell its Medicare Part D plans, the requirements in paragraphs (a) through (e) of this section are applicable. If a Part D sponsor makes payments to third parties, the requirements in paragraph (f) of this section are applicable.

(a) *Definitions.* For purposes of this section, the following definitions are applicable:

Compensation. (i) Includes monetary or non-monetary remuneration of any kind relating to the sale or renewal of a plan or product offered by a Part D sponsor including, but not limited to the following:

(A) Commissions.

(C) Bonuses.

(C) Gifts.

(D) Prizes or Awards.

(E) Referral or Finder fees.

(ii) Does not include any of the following:

(A) Payment of fees to comply with State appointment laws, training, certification, and testing costs.

(B) Reimbursement for mileage to, and from, appointments with beneficiaries.

(C) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

Fair market value (FMV) means, for purposes of evaluating agent and broker compensation under the requirements of this section only, the amount that CMS determines could reasonably be expected to be paid for an enrollment or continued enrollment into a Part D plan. FMV for an upcoming year is calculated by adding the current year FMV and the product of the current year FMV and the Annual Percentage Increase for Part D, which is published for each year in the rate announcement issued pursuant to § 422.312 of this chapter.

Initial enrollment year means the first year that a beneficiary is enrolled in a plan vs. subsequent years (c.f., *renewal year*) that a beneficiary remains enrolled in a plan.

Like plan type means one of the following:

(i) PDP replaced with another PDP.

(ii) MA or MA–PD replaced with another MA or MA–PD.

(iii) Cost plan replaced with another cost plan.

Plan year and *enrollment year* mean the year beginning January 1 and ending December 31.

Renewal year means all years following the initial enrollment year in the same plan or in different plan that is a like plan type.

Unlike plan type means one of the following:

(i) An MA or MA–PD plan to a PDP or Section 1876 Cost Plan.

(ii) A PDP to a Section 1876 Cost Plan or an MA or MA–PD plan.

(iii) A Section 1876 Cost Plan to an MA or MA–PD plan or PDP.

(b) *Agent/broker requirements.* Agents and brokers who represent Part D sponsors must follow the requirements in paragraphs (b)(1) through (3) of this section. Representation includes selling products (including Medicare Advantage plans, Medicare Advantage-Prescription Drug plans, Medicare Prescription Drug plans, and section 1876 Cost plans) as well as outreach to existing or potential beneficiaries and answering or potentially answering questions from existing or potential beneficiaries.

(1) Be licensed and appointed under State law (if required under applicable State law).

(2) Be trained and tested annually as required under paragraph (c)(4) of this section, and achieve an 85 percent or higher on all forms of testing.

(3) Secure and document a Scope of Appointment prior to meeting with potential enrollees.

(c) *Part D sponsor oversight.* Part D sponsors must oversee first tier, downstream, and related entities that represent Part D sponsor to ensure agents/brokers abide by all applicable State and Federal laws, regulations, and requirements. Part D sponsors must do all of the following:

(1) As required under applicable State law, employ as marketing representatives only individuals who are licensed by the State to conduct marketing (as defined in this subpart) in that State, and whom the Part D sponsor has informed that State it has appointed,

consistent with the appointment process provided for under State law.

(2) As required under applicable State law, report the termination of an agent/broker to the State and the reason for termination if required by state law.

(3) Report to CMS all enrollments made by unlicensed agents/brokers and for-cause terminations of agent/brokers.

(4) On an annual basis, provide agent/broker training and testing on Medicare rules and regulations, the plan products that agents and brokers will sell including any details specific to each plan product, and relevant State and Federal requirements.

(5) On an annual basis by the last Friday in July, report to CMS whether the Part D sponsor intends to use employed, captive, and/or independent agents/brokers in the upcoming plan year and the specific rates or range of rates the plan will pay independent agents/brokers. Following the reporting deadline, Part D sponsor may not change their decisions related to agent/broker type, or their compensation rates and ranges, until the next plan year.

(6) On an annual basis by October 1, have in place full compensation structures for the following plan year. The structure must include details on compensation dissemination, including specifying payment amounts for initial enrollment year and renewal year compensation.

(7) Submit agent/broker marketing materials to CMS through HPMS prior to use, following the requirements for marketing materials in this subpart.

(8) Ensure agents and brokers do not charge beneficiaries a marketing fee.

(9) Establish and maintain a system for confirming that:

(i) Beneficiaries enrolled by agents/brokers understand the product, including the rules applicable under the plan.

(ii) Agent/brokers appropriately complete Scope of Appointment records for all marketing appointments (including telephonic and walk-in).

(10) Demonstrate that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(11) Must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

(d) *Compensation requirements.* Part D sponsors must ensure they meet the requirements in paragraphs (d)(1) through (5) of this section in order to pay compensation. These compensation requirements only apply to independent agent/brokers.

(1) *General rules.* (i) MA organizations may only pay agents/brokers who meet the requirements in paragraph (b) of this section.

(ii) Part D sponsors may determine, through their contracts, the amount of compensation to be paid, provided it does not exceed limitations outlined in this section.

(iii) Part D sponsors may determine their payment schedule (for example, monthly or quarterly). Payments (including payments for AEP enrollments) must be made during the year of the beneficiary's enrollment.

(iv) Part D sponsors may only pay compensation for the number of months a member is enrolled.

(2) *Initial enrollment year compensation.* For each enrollment in an initial enrollment year, Part D sponsors may pay compensation at or below FMV.

(i) Part D sponsors may pay either a full or pro-rated initial enrollment year compensation for:

(A) A beneficiary's first year of enrollment in any plan; or

(B) A beneficiary's move from an employer group plan to a non-employer group plan (either within the same parent organization or between parent organizations).

(ii) Part D sponsors must pay pro-rate initial enrollment year compensation for:

(A) A beneficiary's plan change(s) during their initial enrollment year.

(B) A beneficiary's selection of an ''unlike plan type'' change. In that case, the new plan would only pay the months that the beneficiary is enrolled, and the previous plan would recoup the months that the beneficiary was not in the plan.

(3) *Renewal compensation.* For each enrollment in a renewal year, Part D sponsors may pay compensation at an amount up to 50 percent of FMV.

(i) Part D sponsors may pay compensation for a renewal year:

(A) In any year following the initial enrollment year the beneficiary remains in the same plan; or

(B) When a beneficiary enrolls in a new ''like plan type''.

(ii) [Reserved]

(4) *Other compensation scenarios.* (i) When a beneficiary enrolls in a PDP, the Part D sponsor may pay only the PDP compensation (and not compensation for MA enrollment under § 422.2274 of this chapter).

(ii) When a beneficiary enrolls in both a section 1876 Cost Plan and a stand-alone PDP, the 1876 Cost Plan sponsor may pay compensation for the cost plan enrollment and the Part D sponsor must pay compensation for the Part D enrollment.

(iii) When a beneficiary enrolls in a MA-only plan and a PDP, the MA plan may pay for the MA plan enrollment and the Part D sponsor may pay for the PDP enrollment.

(5) *Additional compensation, payment, and compensation recovery requirements (Charge-backs).* (i) Part D sponsors must retroactively pay or recoup funds for retroactive beneficiary changes for the current and previous calendar years. Part D sponsors may choose to recoup or pay compensation for years prior to the previous calendar year, but they must do both (recoup amounts owed and pay amounts due during the same year).

(ii) Compensation recovery is required when:

(A) A beneficiary makes any plan change (regardless of the parent organization) within the first 3 months of enrollment (known as rapid disenrollment), except as noted in paragraph (d)(5)(iii) of this section.

(B) Any other time period a beneficiary is not enrolled in a plan, but the plan paid compensation based on that time period.

(iii) Rapid disenrollment compensation recovery does not apply when:

(A) A beneficiary enrolls effective October 1, November 1, or December 1 and subsequently uses the Annual Election Period to change plans for an effective date of January 1.

(B) A beneficiary's enrollment change is not in the best interests of the Medicare program, including for the following reasons:

(*1*) Other creditable coverage (for example, an employer plan).

(*2*) Moving into or out of an institution.

(*3*) Gain or loss of employer/union sponsored coverage.

(*4*) Plan termination, non-renewal, or CMS imposed sanction.

(*5*) To coordinate with Part D enrollment periods or the State Pharmaceutical Assistance Program.

(*6*) Becoming LIS or dually eligible for Medicare and Medicaid.

(*7*) Qualifying for another plan based on special needs.

(*8*) Due to an auto, facilitated, or passive enrollment.

(*9*) Death.

(*10*) Moving out of the service area.

(*11*) Non-payment of premium.

(*12*) Loss of entitlement or retroactive notice of entitlement.

(*13*) Moving into a 5-star plan.

(*14*) Moving from an LPI plan into a plan with three or more stars.

(iv)(A) When rapid disenrollment compensation recovery applies, the entire compensation must be recovered.

(B) For other compensation recovery, plans must recover a pro-rated amount of compensation (whether paid for an initial enrollment year or renewal year) from an agent/broker equal to the number of months not enrolled.

(*1*) If a plan has paid full initial compensation, and the enrollee disenrolls prior to the end of the enrollment year, the total number of months not enrolled (including months prior to the effective date of enrollment) must be recovered from the agent/broker.

(*2*) Example: A beneficiary enrolls upon turning 65 effective April 1 and disenrolls September 30 of the same year. The plan paid full initial enrollment year compensation. Recovery is equal to 6/12ths of the initial enrollment year compensation (for January through March and October through December).

(e) *Payments to third parties.* (1) Payments made to third parties (that is, entities other than individual agents/brokers) for services other than enrollment of beneficiaries (for example, training customer service, agent recruitment, or operational overhead) must not exceed FMV.

(2) Administrative payments to third parties can be based on enrollment, provided payments are at or below FMV.

■ 104. Section 423.2305 is amended by revising the definition for ''Applicable discount'' to read as follows.

§ 423.2305 Definitions.

* * * * *

Applicable discount means 50 percent or, with respect to a plan year after plan year 2018, 70 percent of the portion of the negotiated price (as defined in this section) of the applicable drug of a manufacturer that falls within the coverage gap and that remains after such negotiated price is reduced by any supplemental benefits that are available.

* * * * *

■ 105. Section 423.2440 is revised to read as follows:

§ 423.2440 Credibility adjustment.

(a) A Part D sponsor may add the credibility adjustment specified under paragraph (e) of this section to a contract's MLR if the contract's experience is partially credible, as defined in paragraph (d)(1) of this section.

(b) A Part D sponsor may not add a credibility adjustment to a contract's MLR if the contract's experience is fully credible, as defined in paragraph (d)(2) of this section.

(c) For those contract years for which a contract has non-credible experience, as defined in paragraph (d)(3) of this section, sanctions under § 423.2410(b) through (d) will not apply.

(d)(1) A contract's experience is partially credible if it is based on the experience of at least 4,800 member months and fewer than or equal to 360,000 member months.

(2) A contract's experience is fully credible if it is based on the experience of more than 360,000 member months.

(3) A contract's experience is non-credible if it is based on the experience of fewer than 4,800 member months.

(e) The credibility adjustment for partially credible experience is determined based on the number of member months for all enrollees under the contract and the factors shown in Table 1 of this section. When the number of member months used to determine credibility exactly matches a member month category listed in Table 1 of this section, the value associated with that number of member months is the credibility adjustment. The credibility adjustment for a number of member months between the values shown in Table 1 of this section is determined by linear interpolation.

TABLE 1 TO § 423.2440—CREDIBILITY ADJUSTMENTS FOR PART D CONTRACTS

Member months	Credibility adjustment (additional percentage points)
<4,800	N/A (Non-credible).
4,800	8.4%.
12,000	5.3%.
24,000	3.7%.
48,000	2.6%.
120,000	1.7%.
240,000	1.2%.
360,000	1.0%.
>360,000	0.0% (Fully credible).

PART 455—PROGRAM INTEGRITY: MEDICAID

■ 106. The authority citation for part 455 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 107. Section 455.2 is amended by—

■ a. In the definition of ''Credible allegation of fraud,'' revising paragraph (1); and

■ b. Adding the definition of ''Fraud hotline tip'' in alphabetical order.

The revision and addition read as follows:

§ 455.2 Definitions.

* * * * *

Credible allegation of fraud. * * *

(1) Fraud hotline tips verified by further evidence.

* * * * *

Fraud hotline tip. A fraud hotline tip is a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

* * * * *

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 108. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f).

■ 109. Section 460.6 is amended by revising the definition of ''Services'' to read as follows:

§ 460.6 Definitions.

* * * * *

Service, as used in this part, means all services that could be required under § 460.92, including items and drugs.

* * * * *

■ 110. Section 460.56 is added to subpart D to read as follows:

§ 460.56 Procedures for imposing sanctions and civil money penalties.

CMS provides notice and a right to request a hearing according to the procedures set forth in either of the following:

(a) Section 422.756(a) and (b) of this chapter if CMS imposes a suspension of enrollment or payment under § 460.42 or § 460.48(b).

(b) Section 422.756(e)(2)(v) of this chapter if CMS imposes civil money penalties under § 460.46.

■ 111. Section 460.92 is revised to read as follows:

§ 460.92 Required services.

(a) The PACE benefit package for all participants, regardless of the source of payment, must include the following:

(1) All Medicare-covered services.

(2) All Medicaid-covered services, as specified in the State's approved Medicaid plan.

(3) Other services determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status.

(b) Decisions by the interdisciplinary team to provide or deny services under paragraph (a) of this section must be based on an evaluation of the participant that takes into account:

(1) The participant's current medical, physical, emotional, and social needs; and

(2) Current clinical practice guidelines and professional standards of care applicable to the particular service.

§ 460.96 [Amended]

■ 112. Section 460.96 is amended by—
■ a. Removing paragraphs (a) and (b); and
■ b. Redesignating paragraphs (c) through (e) as paragraphs (a) through (c).
■ 113. Section 460.98 is amended by—
■ a. Revising paragraph (a);
■ b. Adding a sentence to the end of paragraph (b)(1); and
■ c. Adding paragraphs (b)(4) and (5).

The revision and additions read as follows:

§ 460.98 Service delivery.

(a) *Access to services.* A PACE organization is responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, and must establish and implement a written plan to ensure that care is appropriately furnished.

(b) * * *

(1) * * * These services must be furnished in accordance with § 460.70(a).

* * * * *

(4) Services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs.

(5) The PACE organization must document, track, and monitor the provision of services across all care settings in order to ensure the interdisciplinary team remains alert to the participant's medical, physical, emotional, and social needs regardless of whether services are formally incorporated into the participant's plan of care.

* * * * *

■ 114. Section 460.l02 is amended by revising paragraphs (d)(1) and (d)(2)(ii) to read as follows:

§ 460.102 Interdisciplinary team.

* * * * *

(d) * * *

(1) The interdisciplinary team is responsible for the following:

(i) The initial assessment, periodic reassessments, plan of care, and coordination of 24-hour care delivery.

(ii) Documenting all recommendations for care or services and the reason(s) for not approving or providing recommended care or services, if applicable, in accordance with § 460.210(b).

(2) * * *

(ii) Remaining alert to pertinent input from any individual with direct knowledge of or contact with the participant, including the following:

(A) Other team members.
(B) Participants.
(C) Caregivers.
(D) Employees.
(E) Contractors.
(F) Specialists.

* * * * *

■ 115. Section 460.104 is amended by revising paragraph (d)(2) to read as follows:

§ 460.104 Participant assessment.

* * * * *

(d) * * *

(2) *In response to a service delivery request.* In accordance with § 460.121(h), the PACE organization must conduct an in-person reassessment if it expects to deny or partially deny a service delivery request, and may conduct reassessments as determined necessary for approved services.

* * * * *

■ 116. Section 460.112 is amended by—
■ a. Adding paragraph (b)(4);
■ b. Redesignating paragraph (c)(3) as paragraph (c)(5); and
■ c. Adding new paragraphs (c)(3) and (4).

The additions read as follows:

§ 460.112 Specific rights to which a participant is entitled.

* * * * *

(b) * * *

(4) To contact 1–800–MEDICARE for information and assistance, including to make a complaint related to the quality of care or the delivery of a service.

(c) * * *

(3) To have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines.

(4) To receive necessary care in all care settings, up to and including placement in a long-term care facility when the PACE organization can no longer provide the services necessary to maintain the participant safely in the community.

* * * * *

■ 117. Section 460.121 is added to read as follows:

§ 460.121 Service delivery requests.

(a) *Written procedures.* Each PACE organization must have formal written procedures for identifying and processing service delivery requests in accordance with the requirements of this section.

(b) *What is a service delivery request*—(1) *Requests that constitute a service delivery requests.* Except as provided in paragraph (b)(2) of this section, the following requests constitute service delivery requests:

(i) A request to initiate a service.

(ii) A request to modify an existing service, including to increase, reduce, eliminate, or otherwise change a service.

(iii) A request to continue coverage of a service that the PACE organization is recommending be discontinued or reduced.

(2) *Requests that do not constitute a service delivery request.* Requests to initiate, modify, or continue a service do not constitute a service delivery request if the request is made prior to development of the initial care plan.

(c) *Who can make a service delivery request?* Any of the following individuals can make a service delivery request:

(1) The participant.

(2) The participant's designated representative.

(3) The participant's caregiver.

(d) *Method for making a service delivery request.* An individual may make a service delivery request as follows:

(1) Either orally or in writing.

(2) To any employee or contractor of the PACE organization that provides direct care to a participant.

(e) *Processing a service delivery request.* (1) Except as provided in paragraph (e)(2) of this section, the PACE organization must bring a service delivery request to the interdisciplinary team as expeditiously as the participant's condition requires, but no later than 3 calendar days from the time the request is made.

(2) If a member of the interdisciplinary team is able to approve the service delivery request in full at the time the request is made, the PACE organization—

(i) Must fulfill all of the following:

(A) Notice of the decision to approve a service delivery request requirements specified in paragraph (j)(1) of this section.

(B) Effectuation requirements specified in paragraph (k) of this section.

(C) Recordkeeping requirements specified in paragraph (m) of this section.

(ii) Is not required to process the service delivery request in accordance with paragraphs (f) through (i), (j)(2), and (l) of this section.

(f) *Who must review a service delivery request?* The full interdisciplinary team must review and discuss each service delivery request and decide to approve, deny, or partially deny the request based on that review.

(g) *Interdisciplinary team decision making.* The interdisciplinary team

must consider all relevant information when evaluating a service delivery request, including, but not limited to, the findings and results of any reassessments required in paragraph (h) of this section, as well as the criteria specified in § 460.92(b).

(h) *Reassessments in response to a service delivery request.* (1) If the interdisciplinary team expects to deny or partially deny a service delivery request, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct an in-person reassessment before the interdisciplinary team makes a final decision. The team members performing the reassessment must evaluate whether the requested service is necessary to meet the participant's medical, physical, emotional, and social needs.

(2) The interdisciplinary team may conduct a reassessment prior to approving a service delivery request, either in-person or through the use of remote technology, if the team determines that a reassessment is necessary.

(i) *Notification timeframe.* Except as provided in paragraph (i)(1) of this section, when the interdisciplinary team receives a service delivery request, it must make its decision and notify the participant or their designated representative of its decision as expeditiously as the participant's condition requires, but no later than 3 calendar days after the date the interdisciplinary team receives the request.

(1) *Extensions.* The interdisciplinary team may extend the timeframe for review and notification by up to 5 calendar days if either of the following occur:

(i) The participant or other requestor listed in paragraph (c)(2) or (3) of this section requests the extension.

(ii) The extension is in the participant's interest because the interdisciplinary team needs additional information from an individual not directly employed by the PACE organization that may change the interdisciplinary team's decision to deny a service. The interdisciplinary team must document the circumstances that led to the extension and demonstrate how the extension is in the participant's best interest.

(2) *Notice of extension.* When the interdisciplinary team extends the timeframe, it must notify the participant or their designated representative in writing. The notice must explain the reason(s) for the delay and must be issued as expeditiously as the participant's condition requires, but no later than 24 hours after the IDT decides to extend the timeframe.

(j) *Notification requirements*—(1) *Notice of decisions to approve a service delivery request.* If the interdisciplinary team makes a determination to approve a service delivery request, it must provide the participant or the designated representative either oral or written notice of the determination. Notice of any decision to approve a service delivery request must explain the conditions of the approval in understandable language, including when the participant may expect to receive the approved service.

(2) *Notice of decisions to deny a service delivery request.* If the interdisciplinary team decides to deny or partially deny a service, it must provide the participant or the designated representative both oral and written notice of the determination. Notice of any denial must—

(i) State the specific reason(s) for the denial, including why the service is not necessary to maintain or improve the participant's overall health status, taking into account the participant's medical, physical, emotional, and social needs, and the results of the reassessment(s) in understandable language.

(ii) Inform the participant or designated representative of his or her right to appeal the decision under § 460.122.

(iii) Describe the standard and expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services as specified in § 460.122.

(iv) For a Medicaid participant, inform the participant of both of the following, as specified in § 460.122(e)(1):

(A) His or her right to continue receiving disputed services during the appeals process until issuance of the final determination.

(B) The conditions for continuing to receive disputed services.

(k) *Effectuation requirements.* If the interdisciplinary team approves a service delivery request, in whole or in part, the PACE organization must provide the approved service as expeditiously as the participant's condition requires, taking into account the participant's medical, physical, emotional, and social needs. The interdisciplinary team must explain when the participant may expect to receive the service in accordance with paragraph (j)(1) of this section.

(l) *Effect of failure to meet the processing timeframes.* If the interdisciplinary team fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant's request must be automatically processed by the PACE organization as an appeal in accordance with § 460.122.

(m) *Recordkeeping.* The PACE organization must establish and implement a process to document, track, and maintain records related to all processing requirements for service delivery requests received both orally and in writing. These records must be available to the interdisciplinary team to ensure that all members remain alert to pertinent participant information.

■ 118. Section 460.122 is amended by—

■ a. Revising the introductory text and paragraphs (b) and (c)(1), (2), and (4);

■ b. Redesignating paragraphs (c)(5) and (6) as paragraphs (c)(6) and (7), respectively;

■ c. Adding a new paragraph (c)(5);

■ d. Revising paragraph (d);

■ e. Redesignating paragraphs (g) through (i) as paragraphs (h) through (j), respectively;

■ f. Adding a new paragraph (g); and

■ g. Revising newly redesignated paragraph (h).

The revisions and additions read as follows:

§ 460.122 PACE organization's appeals process.

For purposes of this section, an appeal is a participant's action taken with respect to the PACE organization's noncoverage of, or nonpayment for, a service including denials, reductions, or termination of services. A request to initiate, modify or continue a service must first be processed as a service delivery request under § 460.121 before the PACE organization can process an appeal under this section.

* * * * *

(b) *Notification of participants.* Upon enrollment, at least annually thereafter, and whenever the interdisciplinary team denies a service delivery request or other request for services or payment, the PACE organization must give a participant written information on the appeals process.

(c) * * *

(1) Timely preparation and processing of a written denial of coverage or payment as provided in § 460.121(g).

(2) How a participant or their designated representative files an appeal, including procedures for accepting oral and written appeal requests.

* * * * *

(4) Review of an appeal by an appropriate third party reviewer or committee. An appropriate third party reviewer or member of a review committee must be an individual who meets all of the following:

(i) Appropriately credentialed in the field(s) or discipline(s) related to the appeal.

(ii) An impartial third party who meets both of the following:

(A) Was not involved in the original action.

(B) Does not have a stake in the outcome of the appeal.

(5) The distribution of written or electronic materials to the third party reviewer or committee that, at a minimum, explain all of the following:

(i) Services must be provided in a manner consistent with the requirements in §§ 460.92 and 460.98.

(ii) The need to make decisions in a manner consistent with how determinations under section 1862(a)(1)(A) of the Act are made.

(iii) The rules in § 460.90(a) that specify that certain limitations and conditions applicable to Medicare or Medicaid or both benefits do not apply.

* * * * *

(d) *Opportunity to submit evidence.* A PACE organization must give all parties involved in the appeal a reasonable opportunity to present evidence related to the dispute, in person, as well as in writing.

* * * * *

(g) *Notification.* A PACE organization must give all parties involved in the appeal appropriate written notification of the decision to approve or deny the appeal.

(1) *Notice of a favorable decision.* Notice of any favorable decision must explain the conditions of the approval in understandable language.

(2) *Notice of adverse decisions.* (i) If an appeal decision is partially or fully adverse to a participant, the PACE organization must provide the participant with written notification of the decision. Notice of any denial must—

(A) State the specific reason(s) for the denial;

(B) Explain the reason(s) why the service would not improve or maintain the participant's overall health status;

(C) Inform the participant of his or her right to appeal the decision; and

(D) Describe the external appeal rights under § 460.124.

(ii) If an appeal decision is partially or fully adverse to a participant, at the same time the decision is made, the PACE organization must notify the following:

(A) CMS.

(B) The State administering agency.

(C) The participant.

(h) *Actions following a favorable decision.* A PACE organization must furnish the disputed service as expeditiously as the participant's health condition requires if a determination is made in favor of the participant on appeal.

* * * * *

■ 119. Section 460.124 is revised to read as follows:

§ 460.124 Additional appeal rights under Medicare or Medicaid.

A PACE organization must inform a participant in writing of his or her appeal rights under Medicare or Medicaid managed care, or both, assist the participant in choosing which to pursue if both are applicable, and forward the appeal to the appropriate external entity.

(a) *Appeal rights under Medicare.* Medicare participants have the right to a reconsideration by an independent review entity.

(1) A written request for reconsideration must be filed with the independent review entity within 60 calendar days from the date of the decision by the third party reviewer under § 460.122.

(2) The independent outside entity must conduct the review as expeditiously as the participant's health condition requires but must not exceed the deadlines specified in the contract.

(3) If the independent review entity conducts a reconsideration, the parties to the reconsideration are the same parties described in § 460.122(c)(2), with the addition of the PACE organization.

(b) *Appeal rights under Medicaid.* Medicaid participants have the right to a State Fair Hearing as described in part 431, subpart E, of this chapter.

(c) *Appeal rights for dual eligible participants.* Participants who are eligible for both Medicare and Medicaid have the right to external review by means of either the Independent Review Entity described in paragraph (a) of this section or the State Fair Hearing process described in paragraph (b) of this section.

■ 120. Section 460.200 is amended by—

■ a. Redesignating paragraphs (b) introductory text and (b)(1) through (4) as paragraphs (b)(1) introductory text and (b)(1)(i) through (iv), respectively;

■ b. Adding a new paragraph (b)(2); and

■ c. Revising paragraph (d).

The addition and revision read as follows:

§ 460.200 Maintenance of records and reporting of data.

* * * * *

(b) * * *

(2) CMS and the State administering agency must be able to obtain, examine or retrieve the information specified at paragraph (b)(1) of this section, which may include reviewing information at the PACE site or remotely. PACE organizations may also be required to upload or electronically transmit information, or send hard copies of required information by mail.

* * * * *

(d) *Safeguarding data and records.* PACE organization must do all of the following:

(1) Establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration.

(2) Maintain all written communications received from participants or other parties in their original form when the communications relate to a participant's care, health, or safety in accordance with § 460.210(b)(6).

* * * * *

■ 121. Section 460.210 is amended by—

■ a. Redesignating paragraphs (b)(4) through (12) as (b)(7) through (15); and

■ b. Adding new paragraphs (b)(4) through (6).

The additions read as follows:

§ 460.210 Medical records.

* * * * *

(b) * * *

(4) All recommendations for services made by employees or contractors of the PACE organization, including specialists.

(5) If a service recommended by an employee or contractor of the PACE organization, including a specialist, is not approved or provided, the reason(s) for not approving or providing that service.

(6) Original documentation of any written communication the PACE organization receives relating to the care, health or safety of a participant, in any format (for example, emails, faxes, letters, etc.) and including, but not limited to the following:

(i) Communications from the participant, his or her designated representative, a family member, a caregiver, or any other individual who provides information pertinent to a participant's health or safety or both.

(ii) Communications from an advocacy or governmental agency such as Adult Protective Services.

* * * * *

Dated: January 13, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: January 24, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–02085 Filed 2–5–20; 4:15 pm]

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Department of Transportation

Federal Railroad Administration

49 CFR Part 271

Risk Reduction Program; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 271

[Docket No. FRA–2009–0038, Notice No. 7]

RIN 2130–AC11

Risk Reduction Program

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: FRA is issuing this final rule to require each Class I freight railroad and each freight railroad with inadequate safety performance to develop and implement a Risk Reduction Program (RRP) to improve the safety of its operations. RRP is a comprehensive, system-oriented approach to safety that determines a railroad operation's level of risk by identifying and analyzing applicable hazards, and involves developing plans to mitigate, if not eliminate, that risk. Each railroad has flexibility to tailor an RRP to its specific railroad operations. Each railroad shall implement its RRP under a written RRP plan that FRA has reviewed and approved. Each railroad shall conduct an annual internal assessment of its RRP, and FRA will audit a railroad's RRP processes and procedures.

DATES: This final rule is effective April 20, 2020.

ADDRESSES: *Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* at any time or visit U.S. Department of Transportation, Docket Operations, 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 FURTHER INFORMATION CONTACT: Miriam Kloeppel, Staff Director, Risk Reduction Program Division, U.S. Department of Transportation, Federal Railroad Administration, Office of Railroad Safety, 1200 New Jersey Avenue SE, Washington, DC 20590 (telephone: 202–493–6224), *Miriam.Kloeppel@dot.gov;* or Elizabeth Gross, Attorney Adviser, U.S. Department of Transportation, Federal Railroad Administration, Office of Chief Counsel, 1200 New Jersey Avenue SE, Washington, DC 20590 (telephone: 202–493–1342), *Elizabeth.Gross@dot.gov.*

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I. Executive Summary

A. Statutory Authority for This Rulemaking

FRA's general authority to issue rules on railroad safety is 49 U.S.C. 20103(a), which establishes the authority of the Secretary of Transportation (Secretary) to promulgate regulations for every area of railroad safety. The Secretary has delegated such statutory responsibilities to the Administrator of FRA. *See* 49 CFR 1.89. FRA is issuing this rule to satisfy the statutory mandate in sections 103 and 109 of the Rail Safety Improvement Act of 2008 (RSIA), Public Law 110–432, Division A, 122 Stat. 4848 *et seq.,* codified at 49 U.S.C. 20156 and 20118–20119. The Secretary delegated responsibility to carry out her responsibilities under RSIA sections 103 and 109, and the general responsibility to conduct rail safety rulemakings under 49 U.S.C. 20103(a), to the Administrator of FRA. *See* 49 CFR 1.89(a) and (b).

B. Summary of Major Provisions

FRA is issuing this RRP rule as part of its efforts to continually improve rail safety and to satisfy the statutory mandate in RSIA sections 103 and 109 requiring each Class I freight railroad and each freight railroad with inadequate safety performance to develop and implement an RRP.[1] A railroad not otherwise required to comply with the rule may also voluntarily submit an RRP plan for FRA review and approval. On August 12, 2016, 81 FR 53850, FRA published a separate system safety program (SSP) rule implementing this mandate for commuter and intercity passenger railroads.

An RRP is implemented by a written risk reduction program plan (RRP plan). The RRP rule sets forth various elements that a railroad's RRP plan must contain to properly implement an RRP. As part of its RRP plan, a railroad must also

[1] FRA understands that each railroad subject to this RRP rule has a unique operating system, and not all railroads have the same amount of resources. Best practices for implementing an RRP will therefore differ from railroad to railroad. Accordingly, this rule does not establish prescriptive requirements that may be appropriate for one railroad but unworkable for another. Instead, the rule establishes general, performance-based requirements. This approach provides each railroad flexibility to tailor those requirements to its specific operations.

describe the various procedures and processes for implementing this rule's requirements. This includes procedures and processes for, but not limited to, the following RRP components: Risk-based hazard management program; safety performance evaluation; safety outreach; technology implementation plan; RRP employee/contractor training; railroad employee involvement; and internal assessment.

The main components of an RRP are the risk-based hazard management program and risk-based hazard analysis. A properly implemented risk-based hazard management program and risk-based hazard analysis will identify the hazards and resulting risks on the railroad's system, develop methods to mitigate or eliminate (if practicable) these hazards and risks, and set forth a plan to implement these methods. As part of its RRP, a railroad will also consider various technologies that may mitigate or eliminate the identified hazards and risks.

An RRP will affect almost all facets of a railroad's operations. To ensure all railroad employees an RRP directly affects have an opportunity to provide input on the development, implementation, and evaluation of a railroad's RRP, the rule requires railroads to consult in good faith, and use their best efforts to reach agreement with, such employees on the RRP plan contents and any substantive amendments to the plan. Appendix A to the rule contains guidance on what constitutes good faith and best efforts.

An RRP can be successful only if a railroad engages in a systematic assessment of the hazards and resulting risks on its system. However, a railroad may be reluctant to reveal such hazards and risks if there is the possibility that such information may be used against it in a court proceeding for damages. Congress directed FRA to conduct a study to determine if it was in the public interest to withhold certain information, including the railroad's assessment of its safety risks and its statement of mitigation measures, from discovery and admission into evidence in proceedings for damages involving personal injury and wrongful death. *See* 49 U.S.C. 20119. Further, Congress authorized FRA, by delegation from the Secretary, to prescribe a rule, subject to notice and comment, to address the results of the study. *See* 49 U.S.C. 20119(b). FRA contracted to have the study performed, and the RRP notice of proposed rulemaking (NPRM) addressed the study's results and set forth proposed protections for certain information from discovery, admission into evidence, or use for other purposes in a proceeding for damages. *See* 80 FR 10963–10966 (Feb. 27, 2015).

To minimize the information protected, information a railroad compiles or collects solely to plan, implement, or evaluate an RRP is protected from discovery, admissibility into evidence, or use for other purposes in a proceeding for damages involving personal injury, wrongful death, or property damage. The rule also preempts State discovery rules and sunshine laws which could be used to require the disclosure of protected information in such proceedings. This rule does not protect information a railroad compiles or collects for a purpose unrelated to the railroad's RRP. Under section 20119(b), the information protection provision is not effective until one year after its publication. All other provisions of this final rule will become effective 60 days after the date of publication.

Section 20118 also specifies that certain risk reduction records the Secretary obtains are exempt from the Freedom of Information Act (FOIA) public disclosure requirements. This exemption is subject to two exceptions for disclosure (1) necessary to enforce or carry out any Federal law and (2) when a record is comprised of facts otherwise available to the public and FRA determines disclosure would be consistent with the confidentiality needed for RRPs. *See* 49 U.S.C. 20118. Unless an RSIA exception applies, FRA would not disclose such records in response to a FOIA request. *See* 5 U.S.C. 552(b)(3) and 49 CFR 7.23(c)(3). Therefore, FRA concludes railroad risk reduction records in FRA's possession would be exempted from mandatory disclosure under FOIA unless one of the two exceptions applies.

The rule requires a Class I railroad to submit its RRP plan to FRA for review no later than August 16, 2021. This submission deadline accounts for the statutory one-year delay before the information protection provision becomes effective. Similarly, the rule does not require railroads with inadequate safety performance (ISP railroads) or railroads the Surface Transportation Board (STB) either reclassifies or newly classifies as Class I railroads after the effective date of the final rule to submit RRP plans before the information protection provisions go into effect. An ISP railroad must submit an RRP plan either 180 days after receiving notice FRA determined the ISP railroad had inadequate safety performance or no later than August 16, 2021, whichever is later. A railroad the STB reclassifies or newly classifies as a Class I railroad must submit its RRP either no later than 90 days following the effective date of the classification or reclassification or no later than August 16, 2021, whichever is later.

Within 90 days of receipt of a railroad's RRP plan, FRA will review the plan and determine if it meets the requirements of the rule. If FRA determines the railroad's RRP plan does not comply with the rule, FRA will notify the railroad of how the plan is deficient. The railroad will then have 90 days to correct the deficiencies and resubmit the plan to FRA. Whenever a railroad amends its RRP plan, it must submit the amended plan to FRA for approval and provide a cover letter describing the amendments. (FRA approval is not required for amendments limited to adding or changing a name, title, address, or telephone number of a person, although a railroad must still file the amendment with FRA.) A similar approval process and timeline will apply whenever a railroad substantively amends its RRP.

C. Summary of Costs and Benefits

The rule requires each Class I freight railroad and each ISP railroad to develop and implement an RRP in accordance with a written RRP plan approved by FRA. The rule sets forth required elements that must be included in a railroad's RRP. FRA estimates that the rule's costs for these elements include: Developing a risk-based hazard management program (HMP); documenting an RRP plan and any RRP plan amendments; consulting with directly affected employees and preparing consultation statements; conducting a safety performance evaluation; conducting safety outreach; conducting a technology analysis and developing a technology implementation plan; ensuring employee involvement; providing RRP training; retaining RRP records; and conducting internal assessments. FRA did not estimate the full incremental costs of railroads conducting additional and systematic hazard and risk analyses or implementing actions to mitigate identified hazards and risks. FRA lacks information to reliably estimate such costs because FRA cannot predict the level of hazards and risks on impacted railroads nor the means these railroads will use to mitigate these risks.

Costs begin in the first year of analysis. The below tables summarize the rule's total costs over a ten-year period based on Class I railroads having a 43-percent pre-compliance rate and ISP railroads having no pre-compliance, with a total cost of $40.2 million, using a 7-percent discount rate (present value (PV), 7-percent) (Table 1) and $51.0

million, using a 3-percent discount rate (PV, 3-percent) (Table 2). The annualized costs are $5.7 million (PV, 7-percent) and $5.9 million (PV, 3-percent).

TABLE 1—SUMMARY OF THE RULE'S TOTAL COSTS (TEN-YEAR PERIOD), ASSUMING 43-PERCENT CLASS I PRE-RULE COMPLIANCE; PV, 7-PERCENT

Costs	Class I railroads	ISP railroads	All railroads
Subpart A: General		$7,000	$7,000
Subpart B: RR Programs	35,725,000	2,216,000	37,941,000
Subpart C: RRP Plans	656,000	1,053,000	1,709,000
Subpart D: Review and Approval of Plans	2,000	7,000	9,000
Subpart E: Internal Assessments	171,000	312,000	483,000
Subpart F: External Audits	28,000	32,000	60,000
Total Cost, 7% present value	36,582,000	3,627,000	40,209,000
Annualized, 7%	5,210,000	516,000	5,726,000

TABLE 2—SUMMARY OF THE RULE'S TOTAL COSTS (TEN-YEAR PERIOD), ASSUMING 43-PERCENT CLASS I PRE-RULE COMPLIANCE; PV, 3-PERCENT

Costs	Class I railroads	ISP railroads	All railroads
Subpart A: General		$9,000	$9,000
Subpart B: RR Programs	45,156,000	3,011,000	48,167,000
Subpart C: RRP Plans	771,000	1,329,000	2,100,000
Subpart D: Review and Approval of Plans	2,000	8,000	10,000
Subpart E: Internal Assessments	230,000	413,000	643,000
Subpart F: External Audits	37,000	43,000	80,000
Total Cost, 3% present value	46,197,000	4,813,000	51,000,000
Annualized, 3%	5,416,000	564,000	5,979,000

Benefits that come from the final rule will vary from railroad to railroad. These benefits are based on each railroad's organizational structure, the ability for labor and management to collaborate, and the steps the railroad takes to implement hazard analysis and mitigation. FRA could not reliably predict the specific risks that each freight railroad will identify, the actions each freight railroad will take to mitigate such risks, or the success rate of such actions. Therefore, this analysis qualitatively describes benefits. Details on the estimated benefits of this final rule can be found in the rule's Regulatory Impact Analysis (RIA), which FRA has prepared and placed in the docket (docket no. FRA–2009–0038).[2]

FRA expects that the final rule will increase the effectiveness of railroad hazard mitigation strategies, which will reduce the frequency of accidents and incidents on the general railroad system. FRA also expects that the final rule will result in increased employee morale and improved working conditions, which will improve railroad productivity. These benefits will result because the final rule:

(1) Ensures that railroads keep their RRPs current and in place;

(2) Improves safety culture;

(3) Requires ongoing employee involvement and proactive collaboration between labor and management; and

(4) Provides information protection which allows for a systematic risk-based hazard analysis.

The final rule requires each Class I railroad to have a fully implemented RRP within five years of the rule's effective date and requires the first set of ISP railroads to implement all portions of their RRPs within six years after the final rule's effective date.[3] FRA anticipates that railroads may implement some components of their RRP plan before the required implementation dates specified in the final rule. Therefore, this analysis estimates that the final rule will start generating benefits in the fourth year (year 2022), when Class I railroads will have substantially implemented their RRPs. As previously discussed, Class I railroads have in place existing activities related to the final rule's required components. The existing levels of pre-rule compliance reduce the size of potential benefits that follow from issuing the final rule.

II. Abbreviations

The following abbreviations are used in this preamble and are collected here for the convenience of the reader:

CFR Code of Federal Regulations
DOT United States Department of Transportation
FMP Fatigue Management Plan
FOIA Freedom of Information Act
FR Federal Register
FRA Federal Railroad Administration
HMP Hazard Management Program
NPRM Notice of Proposed Rulemaking
OST Office of the Secretary, United States Department of Transportation
PTC Positive Train Control
Pub. L. Public Law
RRP Risk Reduction Program
RSAC Railroad Safety Advisory Committee

[2] Document inspection and copying facilities are available at Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC 20590. The docket for this rulemaking is also available online at *www.regulations.gov* under docket no. FRA–2009–0038.

[3] An ISP railroad should begin to realize benefits approximately three years after FRA approves its RRP plan, the point when the final rule requires the ISP railroad to have fully implemented its RRP. The final rule requires each ISP railroad that is part of the first group of ISP railroads to implement in full an RRP by the sixth year.

RSIA Railroad Safety Improvement Act of 2008, Public Law 110–432, Div. A, 122 Stat. 4848
Secretary Secretary of Transportation
SSP System Safety Program
U.S.C. United States Code

III. Background and History

A. What is a Risk Reduction Program?

Risk reduction is a comprehensive, system-oriented approach to improving safety by which an organization formally identifies and analyzes applicable hazards and takes action to mitigate, if not eliminate, the risks associated with those hazards. It provides a railroad with a set of decision making processes and procedures that can help it plan, organize, direct, and control its railroad operations in a way that enhances safety and promotes compliance with regulatory standards. As such, risk reduction is a form of safety management system, which is a term generally referring to a comprehensive, process-oriented approach to managing safety throughout an organization.

The principles and processes of risk reduction are based on safety management systems (SMS) developed to assure high safety performance in various industries, including aviation, passenger railroads, the nuclear industry, and other industries with the potential for catastrophic accidents. SMS methodologies have evolved through experience to include a multitude of equally important elements without which the organization's safety performance does not reliably improve. These SMS elements are typically grouped into the following larger descriptive categories: (1) An organization-wide safety policy; (2) formal methods for identifying hazards and prioritizing and mitigating risks associated with those hazards; (3) data collection, data analysis, and evaluation processes to determine the effectiveness of mitigation strategies and to identify emerging hazards; and (4) outreach, education, and promotion of an improved safety culture within the organization.

B. Summary of NPRM

On February 27, 2015, FRA published the NPRM proposing to require each Class I freight railroad and each freight railroad with inadequate safety performance to develop and implement an RRP to improve the safety of their railroads operations. *See* 80 FR 10950. The NPRM proposed the following RRP components: (1) A risk-based hazard management program; (2) safety performance evaluation; (3) safety outreach; (4) technology analysis and technology implementation plan; (5) implementation and support training; (6) internal assessments; and (7) external audits. The NPRM also proposed requiring a railroad to submit its RRP plan to FRA for review and approval and to consult in good faith and use its best efforts to reach agreement with all its directly affected employees on the contents of the RRP plan. Finally, the NPRM proposed to protect certain RRP information from discovery, admission into evidence, or use for other purposes in a proceeding for damages.

In addition to these specific proposals, the NPRM contained a general background discussion of risk reduction programs and discussed FRA's experience with risk reduction programs, such as passenger railroads that have implemented system safety programs. The NPRM also summarized the rulemaking proceedings that occurred before NPRM publication, including publication of an advanced notice of proposed rulemaking (ANPRM) and related proceedings of the RSAC RRP Working Group. FRA is providing relevant updates to these discussions below.

C. Proceedings Since the NPRM

The comment period for the NPRM closed on April 28, 2015. As several commenters requested, FRA held a public meeting on August 27, 2015 and invited interested parties to present oral statements and to offer information and views on the proposed rulemaking at the hearing. FRA placed the transcript for the public hearing in the docket for this rulemaking. FRA also reopened the public comment period from July 30, 2015 through September 10, 2015 and from September 15, 2015 through September 18, 2015 to accommodate the public hearing and to allow interested parties to submit comments in response to views and information provided at the public hearing.

On September 29, 2015, the RSAC RRP Working Group met to review and discuss comments received in response to both the NPRM and the public hearing. FRA then reopened the comment period for this rulemaking from October 7, 2015 through October 21, 2015 to allow interested parties to submit written comments in response to views or information provided at the RRP Working Group meeting.

D. Regulatory Review

DOT has invited the public to provide input on existing rules and other agency actions that are good candidates for repeal, replacement, suspension, or modification. *See* 82 FR 45750 (Oct. 2, 2017). As appropriate, this final rule responds to comments submitted in response to DOT's regulatory review initiative that address railroad safety risk reduction programs under the RSIA.

E. Summary of Comments

FRA received 80 comments in response to the NPRM, the public hearing, and the RRP Working Group Meeting. Some interested parties submitted multiple comments. FRA received comments from a variety of entities, including railroads, trade associations, non-profit employee labor organizations, State elected representatives, non-profit advocacy organizations, and private citizens.[4] Various interested labor organizations (Labor Organizations I) jointly filed a comment in response to the NPRM,[5] and a different group of labor organizations (Labor Organizations II) also filed a comment in response to information presented at the RRP Working Group meeting.[6] Finally, some organizations also filed a joint comment (Group Letter).[7] Additionally, in response to DOT's regulatory review initiative, American Short Line and

[4] Commenters included: Academy of Railroad Labor Attorneys; American Association of Justice; American Public Transportation Association; American Short Line and Regional Railroad Association; Association of American Railroads; Association of Tourist Railroads and Railway Museums; Bureau of Locomotive Engineers and Trainmen (BLET); California State Senator (3rd District) Lois Wolk; Chesapeake Climate Action Network; City of Portland, Oregon; DNV GL Oil & Gas Risk Advisory Services; Friends of the Earth; International Association of Sheet Metal, Air, Rail and Transportation Workers—Transportation Division (SMART Transportation Division); Mountain Watershed Association; National Safety Council; New Jersey Work Environment Council; North Platte Peer Review Team; Orion's Angels; Public Citizen Texas; Rancho Rail Line; State of Washington Representative (46th Legislative District) Jessyn Farrell; Toxics Use Reduction Institute; Transport Action Canada; Union Pacific Railroad; and 45 individuals.

[5] These included: American Train Dispatchers Association (ATDA); BLET; Brotherhood of Maintenance of Way Employes Division (BMWED); Brotherhood of Railroad Signalmen (BRS); Brotherhood Railway Carmen Division TCU/IAM; SMART Transportation Division; and Transport Workers Union of America (TWU).

[6] These included: BLET; BMWED; BRS; SMART Transportation Division; and Transportation Communication Union (TCU).

[7] Group Letter organizations were: Alliance for Justice; Bay Area Refinery Corridor Coalition; Blue Ridge Environmental Defense League; Center for Effective Government; Center for Justice and Democracy; Citizens Acting for Rail Safety; Citizens for a Clean Harbor; Crockett-Rodeo United to Defend the Environment; Benicians for a Safe and Healthy Community; Delaware Riverkeeper Network; Forest Ethics; Friends of Grays Harbor; Friends of the Earth; Idaho Conservation League; Milwaukee Riverkeeper; Protect All Children's Environment; Public Citizen; United Steelworkers; US PIRG; Sciencecorps; Sierra Club; The SunFlower Alliance; Yolo MoveOn; and Youghiogheny Riverkeeper, Mountain Watershed Association.

Regional Railroad Association (ASLRRA) and the Virginia Railway Express (VRE) each submitted a comment discussing railroad safety risk reduction programs under the RSIA.

Generally, all commenters were in favor of RRP. While the comments contained varying suggestions on the structure and breadth of an RRP, most commenters agreed a properly implemented RRP would increase the safety of railroad operations. Many commenters, however, expressed concern about the FRA proposal to limit the use of some RRP information in legal proceedings for damages. FRA discusses this and other specific comments in further detail below.

E. Update on Other Federal Safety Management System Programs

The RRP NPRM discussed other Federal agencies that had established or proposed safety management system requirements or guidance for regulated entities. Specifically, the NPRM discussed Federal Transit Administration regulations, regulations the Federal Aviation Administration (FAA) proposed, and guidelines the U.S. Department of Defense published. *See* 80 FR 10953 (Feb. 27, 2015). For a discussion of post-NPRM developments with these programs and new Federal safety management system initiatives please see the SSP final rule at 81 FR 53853–53854 (Aug. 12, 2016).

IV. Statutory Background

A. Rail Safety Improvement Act of 2008

RSIA section 103(a) directs the Secretary to issue a regulation requiring Class I railroads, railroad carriers that provide intercity rail passenger or commuter rail passenger transportation (passenger railroads), and railroads with inadequate safety performance to develop, submit to the Secretary for review and approval, and implement a railroad safety risk reduction program. RSIA section 103(a)(4) also states that railroads not required to comply with this rule may voluntarily submit to FRA for approval an RRP plan meeting the requirements. Section 20156 codifies these provisions.

This RRP rule implements section 20156 as it applies to Class I freight railroads, freight railroads with inadequate safety performance, and voluntarily-compliant railroads. The RRP rule is a risk reduction program in that it requires subject railroads to assess and manage risk and to develop proactive hazard management methods to promote safety improvement. The rule contains provisions that, while not explicitly required by the statutory safety risk reduction program mandate, are necessary to properly implement the mandate and are consistent with the intent behind the mandate.

B. Related System Safety and Fatigue Management Plans Rulemakings

This RRP final rule addresses the RSIA sections 103 and 109 RRP mandate for Class I freight railroads and freight railroads with inadequate safety performance. Two separate rulemakings address the mandate for passenger railroads and for Fatigue Management Plans. The NPRM discussed both these rulemakings and how they related to the RRP rulemaking. *See* 80 FR at 10955. FRA published an SSP final rule for passenger railroads on August 12, 2016. *See* 81 FR 53850.[8]

Section 20156(d)(2) states an RRP must include a fatigue management plan (FMP) that meets the requirements of section 20156(f). However, this RRP final rule does not implement this mandate because FRA is addressing FMPs in a separate rulemaking. The RSAC Fatigue Management Plans Working Group (FMP Working Group), which completed its work in September 2013, submitted its recommendations to FRA for further consideration. FRA is currently drafting an FMP NPRM.

Once FRA publishes an FMP rule, FRA will consider any FMP a railroad develops and implements under that rule part of a railroad's RRP or SSP. Before FRA issues an FMP final rule, FRA will approve RRP plans that do not contain an FMP component, if the RRP plan meets all other applicable RRP requirements. A railroad may still, however, elect to use processes and procedures in its RRP plan to address fatigue-related railroad safety issues.

C. Consultation Process Requirements

Section 20156(g)(1) states that a railroad required to establish a safety risk reduction program must ''consult with, employ good faith and use its best efforts to reach agreement with, all of its directly affected employees, including any non-profit employee labor organization representing a class or craft of directly affected employees of the railroad carrier, on the contents of the safety risk reduction program.'' Section 20156(g)(2) further provides that if a railroad and its directly affected employees ''cannot reach consensus on the proposed contents of the plan, then directly affected employees and such organizations may file a statement with the Secretary explaining their views on the plan on which consensus was not reached.'' Section 20156(g)(2) further provides that FRA must consider these views during review and approval of a railroad's RRP plan.

As proposed in the NPRM, the rule implements this mandate by requiring each railroad required to establish an RRP to consult with its directly affected employees (using good faith and best efforts) on the contents of its RRP plan. A railroad must also include a consultation statement in its submitted plan describing how it consulted with its employees. If a railroad and its employees cannot reach consensus, directly affected employees may file a statement with FRA describing their views on the plan.

Like the information protection provisions discussed below, the RRP and SSP rules have essentially identical provisions regarding the consultation process requirements because there was significant discussion during the SSP and RRP RSAC processes on how to implement section 20156(g). FRA worked with the General Passenger Safety Task Force's System Safety Task Group to receive input on how to address the consultation process, with the understanding that FRA would include the same language in both the SSP and RRP NPRMs for review and comment. The minor differences between the consultation provisions in the RRP and SSP rules are discussed in the section-by-section analysis for § 271.207.

D. Risk Reduction Information Protection

1. Exemption From Freedom of Information Act Disclosure

In section 20118, Congress exempted railroad safety analysis records from public disclosure in response to FOIA requests. Generally, FOIA requires a Federal agency to make most records available upon request, unless a record is protected from mandatory disclosure by one of nine exemptions. One of those exemptions, Exemption 3, applies to records specifically exempted from disclosure by statute if the statute requires the matters be withheld from the public in such a manner as to leave no discretion on the issue or establishes particular criteria for withholding or refers to particular types of matters to be withheld. *See* 5 U.S.C. 552(b)(3). *See also* 49 CFR 7.23(c)(3). The NPRM explains FRA's conclusion that section 20118 is a FOIA Exemption 3 statute and, therefore, exempts RRP records in FRA's possession from mandatory disclosure under FOIA, unless one of

[8] On August 30, 2019, FRA issued a final rule extending a stay of the SSP rule's requirements to March 4, 2020. *See* 84 FR 45683 (2019). FRA issued the stay to develop its response to various petitions for reconsideration of the SSP final rule. *Id.*

the two RSIA exceptions discussed above applies. *See* 80 FR at 10957–10958. FRA did not receive any comments questioning its conclusion so FRA refers interested readers to the NPRM's analysis of this conclusion. *Id.*

2. Discovery and Other Use of Risk Analysis Information in Litigation

a. The Statutory Mandate

Section 20119(a) directed FRA to conduct a study to determine whether it is in the public interest to withhold from discovery or admission into evidence in a Federal or State court proceeding for damages involving personal injury or wrongful death against a carrier any information (including a railroad's analysis of its safety risks and its statement of the mitigation measures with which it will address those risks) compiled or collected for the purpose of evaluating, planning, or implementing a risk reduction program. Section 20119(a) required FRA to solicit input from railroads, railroad non-profit employee labor organizations, railroad accident victims and their families, and the general public for the study. Section 20119(b) also states that upon completion of the study, if in the public interest, FRA could prescribe a rule addressing the results of the study. Section 20119(b) states any such rule is not effective until one year after its adoption.

b. The Final Study Report and Its Conclusions

FRA contracted with a law firm, Baker Botts L.L.P. (Baker Botts), to conduct the study for FRA. Various study documents are available for review in public docket no. FRA–2011–0025, which interested parties can access online at *www.regulations.gov.* First, Baker Botts prepared an initial report identifying and evaluating other Federal safety programs that protect safety-related information from use in litigation. *See Report on Federal Safety Programs and Legal Protections for Safety-Related Information,* FRA, docket no. FRA–2011–0025–0002, April 14, 2011. Next, as section 20119(a) requires, FRA published a **Federal Register** document seeking public comment on whether it would be in the public interest to protect certain railroad risk reduction information from use in litigation. *See* 76 FR 26682 (May 9, 2011). Interested parties may view comments received in response to this document in the public docket.

On October 21, 2011, Baker Botts produced a final report on the study. *See Study of Existing Legal Protections for Safety-Related Information and Analysis of Considerations For and Against Protecting Railroad Safety Risk Reduction Program Information* (*Final Study Report*), FRA, docket no. FRA–2011–0025–0031, Oct. 21, 2011. The Final Study Report contains analyses of other Federal programs that protect similar safety-related information, the public comments submitted to the docket, and whether it would be in the public interest, including the interests of public safety and the legal rights of persons injured in railroad accidents, to protect railroad risk reduction information from disclosure during litigation.

The Final Study Report determines that substantial support exists for the conclusion that a rule that protects ''railroad safety risk information from use in civil litigation involving claims for personal injuries or wrongful death would serve the broader public interest.'' *Final Study Report* at 63. The Final Study Report highlights that, in the past, with similar programs, Congress deemed it is in the public's interest to place statutory limitations on disclosing or using certain information used by the Federal Government. *Id.* The safety risk reduction programs that RSIA mandates, according to the Final Study Report, involve public interest considerations similar to the ones Congress has protected through statutory limitations, and courts have upheld these limitations. The Final Study Report explains that many of the public comments submitted to the docket agree that limiting the use of information collected for a safety risk reduction program mandated by RSIA in discovery or litigation would serve the broad public interest by encouraging and facilitating the timely and complete disclosure of safety-related information to FRA. Further, the Final Study Report underscores FRA's statutory duty to protect the broader public interest in ensuring rail safety and concludes that this public interest outweighs the individual interests of future litigants who may bring damage claims against railroads. Therefore, the Final Study Report concludes that

> after balancing all of the considerations that bear upon the public interest . . . the balance weighs in favor of adopting rules prohibiting the admissibility or discovery of information compiled or collected for FRA railroad safety risk reduction programs in a civil action where a plaintiff seeks damages for personal injury or wrongful death.

Id. at 64.

In response to the Final Study Report, the RRP NPRM proposed in § 271.11 to protect any information compiled or collected for the sole purpose of developing, implementing, or evaluating an RRP from discovery, admission into evidence, or consideration for other purposes in a Federal or State court proceeding for damages involving personal injury, wrongful death, or property damage. The NPRM clarified that the protected information would include a railroad's identification of safety hazards, analysis of safety risks, and statement of the mitigation measures for addressing those risks. Protected information could be in the form of plans, reports, documents, surveys, schedules, lists, data, or any other form. FRA received multiple comments in response to the information protections that both the SSP and RRP NPRM proposed and has modified its approach based on these comments. These changes are discussed further in the discussion of comments section and the corresponding section-by-section analysis.

V. Discussion of General Comments

This section discusses general comments FRA received on the RRP NPRM relating to the proposed information protections and the overall nature of the proposed rule. The section-by-section analysis discusses all other comments as they relate to specific sections, including any changes to the rule text FRA made in response.

A. Information Protection

FRA received numerous comments regarding the proposed information protections and has modified the proposed information protections based on both the received comments and the information protection provisions in the SSP final rule. As discussed in the NPRM, this RRP final rule contains an information protection provision substantively identical to the information protection provision in the SSP final rule.[9] *See* 81 FR 53900 (Aug. 12, 2016). FRA believes different RRP and SSP provisions governing information protection would be confusing. Further, the SSP and RRP RSAC processes significantly discussed how to implement the information protections. FRA worked with both the General Passenger Safety Task Force's System Safety Task Group and the RRP Working Group to receive input on how

[9] The minor differences between the RRP and SSP information protections involve the use of ''risk reduction program'' instead of ''system safety program'' and citations to relevant provisions in the RRP rule instead of provisions in the SSP rule. To correct a minor typo in the SSP information protection provision, the RRP information protection provision also uses the term ''proceeding'' instead of ''proceedings.'' No substantive difference is intended by this correction.

the SSP and RRP rules should address information protection, with the understanding that both rules would likely contain the same language.

1. Comments Supporting the Proposed Information Protections

Several commenters agreed with FRA's conclusion that the proposed information protections are necessary, including Association of American Railroads (AAR), American Public Transportation Association (APTA), ASLRRA, Union Pacific Railroad (UP), and Labor Organizations I. These commenters support FRA's position that the litigation protections are necessary for a railroad to engage in a thorough and candid analysis of the hazards and resulting risks on its system. Based on those comments, FRA believes both railroad management and railroad labor generally agree an RRP final rule must have some form of information protections.

2. Comments on Final Study Report

Several commenters questioned the neutrality and the substance of the Baker Botts Final Study Report. Commenters questioning the neutrality of Final Study Report included American Association for Justice (AAJ), Academy of Railroad Labor Attorneys (ARLA), Labor Organizations I, Labor Organizations II, and several individuals. These commenters provided several examples of Baker Botts' alleged bias, including: (1) Citations to Baker Botts' website; (2) a book by William G. Thomas titled *Lawyering for the Railroad: Business, Law, and Power in the South* (Louisiana State University Press, 1999), which describes Baker Botts' historical representation of Southern Pacific Railroad beginning in the later 1800s until sometime in the 1900s; (3) a Baker Botts associate's prior employment with Norfolk Southern Corporation; and (4) a website indicating that Baker Botts was involved in litigation related to the July 6, 2013 rail accident in Lac-Mégantic, Quebec. The commenters did not provide a specific example of Baker Botts representing a railroad in litigation involving claims for damages at the time of the study.

After evaluating these comments, FRA concludes that it complied with all legal requirements, including the RSIA and the Federal Acquisitions Regulations (FAR), in selecting Baker Botts and conducting the study. *See* section 20119 and FAR 48 CFR 9.505 through 9.505–4 and 9.508. Further, FRA has not found any conflict or representation indicating that Baker Botts had a bias in favor of railroad management at the time of the study. For example, any involvement of Baker Botts in Lac-Mégantic-related litigation occurred after the firm completed the study in October 2011. FRA also reviewed *Lawyering for the Railroad: Business, Law, and Power in the South.* Although the book correctly states that Baker Botts represented Southern Pacific railroad beginning in the late 1800s until sometime in the 1900s, the book does not have an example of Baker Botts representing a railroad at the time of the study.

Baker Botts also conducted its own conflict check when submitting its bid in response to FRA's request for proposal (RFP) [10] and only found one matter involving advice it provided to a railroad on environmental issues, not rail safety. Further, Baker Botts, as a law firm, must comply with the legal ethical standards of the appropriate State or risk discipline or disbarment of its attorneys.

AAJ, ARLA, and Labor Organizations II also submitted comments arguing that the Final Study Report did not give adequate consideration to the interests of railroad accident victims, their families, and the general public. For example, ARLA and Labor Organizations II assert the report only focuses on the railroads' alleged interests and why FRA should protect risk reduction information. FRA disagrees and believes the Final Study Report adequately considered the interests of railroad accident victims, their families, and the general public. As section 20119(a) required, FRA solicited input for the report from railroads, railroad nonprofit employee labor organizations, railroad accident victims and their families, and the general public, including AAJ. *See* 76 FR 26682 (May 9, 2011) and Letters Dated May 12, 2011, to Stakeholders Inviting Comments (FRA–2011–0025–0006). In response, FRA received 22 comments representing 25 affected entities, including railroads, AAJ, Public Citizen (a non-profit public interest organization), various railroad non-profit employee labor organizations, and individuals. The Final Study Report summarizes comments both supporting and opposing a rule that would protect risk reduction information. *See generally* Final Study Report at 37–46. The Final Study Report also analyzes the relevant public interest considerations, including considerations opposing a rule limiting discovery and admissibility. *See generally Id.* at 53–63. Specifically, the Final Study Report considers: (1) Victims' compensation; (2) the necessity of a regulation; (3) promoting railroad safety; (4) promoting the reporting of railroad accidents; (5) promoting open government and freedom of information; (6) what kinds of documents a regulation should protect; and (7) administrative procedure. Therefore, FRA concludes the Final Study Report adequately considered the public interest and the rights of railroad accident victims and their families.

3. Comments Against Any Information Protections

Several commenters objected to including any information protections in the final rule. These included AAJ, ARLA, the non-profit organizations represented by the Group Letter, California State Senator Wolk, Washington State Representative Farrell, the City of Portland, and several individuals and other non-profit organizations.

Overall, the primary objections of many commenters opposed to any information protections are that the protections would (1) ignore the importance of transparency in railroad safety and (2) reduce, not improve, railroad safety. FRA disagrees. First, in section 20118, Congress specifically exempted railroad safety analysis records from mandatory disclosure under FOIA, indicating that Congress concluded the benefits of improved railroad safety outweighed the benefits of complete transparency in railroad safety. Second, the information protections will not change the information available to litigants today, as information currently discoverable and admissible will remain discoverable and admissible. Further, the information protections will improve railroad safety by encouraging railroads to engage in a systematic and honest assessment of the hazards and resulting risks on their systems. A railroad's risk-based Hazard Management Program (HMP) will not improve railroad safety if a railroad is reluctant to reveal risks and hazards because a litigant could use that information against the railroad in a court proceeding for damages.

a. Comments That the Information Protections Are Unprecedented

AAJ contends the proposed information protections are unprecedented. While AAJ recognizes certain existing programs have information protections, AAJ argues those programs have two key features: (1) Congress directed disclosure of documents be limited, and (2) limited

[10] FRA's RFP, Solicitation Number DTFR–53–10–R–00008, is available at *https://www.fbo.gov/index?s=opportunity&mode=form&id=56e2462fb07daa6e45155c3be66ddf02&tab=core&tabmode=list.*

disclosure applies predominately to documents actually submitted to a Federal agency. AAJ believes that the RRP information protections do not have either of these key features. ARLA also claims the safety-related statutes and regulations the Final Study Report cites only protect data a governmental agency holds, not a private entity such as a railroad. (FRA notes that not all railroads are private entities.)

While Congress did not set forth specific information protections in section 20119, Congress explicitly gave FRA authority to promulgate such protections. As discussed previously, section 20119(a) directs FRA to conduct a study to determine if certain information protections would be in the public interest, and Congress described the specific parameters of the information protections the study had to consider. Congress then authorized FRA to promulgate a rule, subject to notice and comment, which addresses the results of the study. *Id.* FRA has complied with Congress' mandate and has included information protections in this rule consistent with the specific parameters Congress described. FRA does not believe the information protections are invalid simply because Congress didn't promulgate specific protections.

Additionally, nothing in section 20119 limits the information protections to documents a railroad submits to FRA. Congress' language in section 20119 states that the information protections, depending on the results of the study, could apply to information a railroad does not submit to FRA. Under section 20119(a), the study must consider information protections that would apply to documents a railroad compiles and collects for ''the purpose of planning, implementing, or evaluating a safety risk reduction program.'' Because Congress did not limit the information protections only to documents a railroad submits to FRA, FRA has authority to protect documents a railroad possesses.

Further, nothing in 23 U.S.C. 409 (section 409), the statute FRA used as a model for the proposed information protections, or the Supreme Court's decision in *Pierce County* v. *Guillen,* 537 U.S. 129 (2003) (which upheld the validity and constitutionality of section 409),[11] limits the information protections to documents submitted to the Federal Highway Administration (FHWA) as part of the Hazard Elimination Program. In that case, the Supreme Court did not base its interpretation of section 409 on whether documents were submitted to FHWA. Rather, the Supreme Court held the information protections extended to information because the Hazard Elimination Program required compiling or collection of that information. *See Guillen,* 537 U.S. at 146. Like the statute at issue in that case, because the RSIA requires railroads to compile and collect information for an RRP, it is appropriate to protect any information the railroad compiles or collects for that purpose, even if the railroad never submits that information to FRA.

AAJ claims that in the limited circumstances where provisions have protected data, the provisions have been narrowly tailored and construed. AAJ believes the proposed information protections are overly broad and inconsistent with any other government program that limits some disclosure of evidence.

FRA agrees with AAJ that the information protections must be narrowly tailored and construed. In *Guillen,* the Supreme Court recognized that ''statutes establishing evidentiary privileges must be construed narrowly because privileges impede the search for truth.'' *Guillen* at 144–45. Because section 409 established a privilege, the Court construed it narrowly to the extent the text of the statute permitted. *Id.* at 145. FRA believes the RRP information protections are consistent with the Court's narrow interpretation of section 409. Further, FRA has tailored the RRP protections even more narrowly than section 409 by limiting them to information a railroad originally compiled or collected ''solely'' for the purpose of planning, implementing or evaluating an RRP, as the section-by-section analysis for § 271.11 discusses.

Labor Organizations II commented that, with the exception of section 409, each safety law or regulation the Final Study Report cites allows discovery of information. FRA believes Labor Organizations II's characterization of the Final Study Report is inaccurate because the final report identifies two additional safety statutes prohibiting both the discoverability and the admissibility of information. The first is 49 U.S.C. 6307(b)(2)(B)(i), which specifies reports submitted to DOT's Bureau of Transportation Statistics (BTS) under 49 U.S.C. 6302(b)(3)(B) are ''immune from legal process.''[12] ''Accordingly, no litigant may subpoena the report in discovery or obtain it through any other legal proceeding.'' Final Study Report at 20. The second statute is 46 U.S.C. 6308(a), which protects from discovery marine casualty reports the U.S. Coast Guard creates under 46 U.S.C. 6301.[13]

Further, Labor Organizations II's argument acknowledges that section 409 prohibits discovery. As discussed in the NPRM, FRA believes section 409 is the best model for the RRP information protections because Congress used similar language in section 409 and section 20119 authorizing information protection and because *Guillen* determined section 409 was constitutional. *See* 80 FR at 10963.

ARLA also commented that virtually every safety law the Final Study Report discussed has exceptions to the protection against disclosure and admissibility. FRA notes that the information protections in § 271.11 are narrowly tailored and will not provide blanket protection for all railroad RRP information. The rule excepts from protection several categories of RRP information, such as (1) information discoverable and admissible before publication of the RRP final rule, (2) information another provision of law or regulation requires the railroad to compile or collect, and (3) information a railroad does not use ''solely'' for an RRP purpose. Accordingly, FRA concludes this rule contains several exceptions to the information protections and is not inconsistent with other safety laws with exceptions to protections against discoverability and admission into evidence.

b. Comments That the Information Protections Will Reduce the Rights of Litigants

AAJ argues the RRP information protections will reduce the rights of persons injured in railroad accidents. AAJ asserts that evidence a railroad knew or should have known of a hazard is key in many cases to prove the railroad's liability, particularly for Federal Employers' Liability Act cases. AAJ believes the Final Study Report concluded without analysis that injured people could continue to pursue legal remedies because access to currently discoverable documents would remain

[11] For additional discussion on FRA's decision to base the RRP information protection provisions on section 409 and *Guillen,* FRA refers readers to the NPRM. *See* 80 FR 10963–10964 (Feb. 27, 2015).

[12] The Final Study Report discussed a previous version of section 6307(b)(2)(B)(i), 49 U.S.C. 111(k)(a)(2)(B)(i), repealed in 2012. *See* Pub. L. 112–141, Div. E, Title II, section 52011(c)(1), July 6, 2012, 126 Stat. 895. However, substantively, sections 6307(b)(2)(B)(i) and 111(k)(a)(2)(B)(i) are identical and have the same ''immune from legal process'' language. Because section 6302(b)(3)(B)(vi)(1) requires BTS to collect statistics on ''transportation safety across all modes and modally,'' FRA believes section 6307(b)(2)(B)(i) is a safety law.

[13] Because marine casualty investigations identify the cause of accidents resulting in fatalities, FRA believes section 6308(a) is also a safety law.

discoverable. AAJ does not believe this conclusion is accurate because it contends the information protections may shield the documents/data necessary to show the railroad knew or should have known of the hazard. AAJ also commented that the information protections are one-sided because they shield the railroad from discovery, while permitting the railroad to obtain extensive discovery regarding a plaintiff's knowledge of a hazard or risk. The Chesapeake Climate Action Network (CCAN) expressed similar concerns.

FRA has drafted the RRP information protections so a plaintiff or defendant is no worse off than he or she would have been if the RRP rule never existed. This is consistent with section 409 and the Supreme Court's interpretation of that section. *See Guillen* at 146. To ensure a plaintiff is no worse off, § 271.11(b) has certain exceptions to the information protections. Under § 271.11(b), the information protections are not extended to information compiled or collected for a purpose other than that specifically identified in § 271.11(a). Further, if certain information was discoverable and admissible before the enactment of the RRP rule, § 271.11(b) ensures the information remains discoverable and admissible. This is true even if the railroad (1) continues to compile or collect that information as part of its RRP or (2) stops compiling or collecting that information outside the RRP and then begins to compile or collect that information again as part of its RRP. These exceptions are discussed extensively in the section-by-section analysis for § 271.11(b). These exceptions strike a reasonable balance between ensuring that plaintiffs are no worse than they would have been if the RRP rule had not existed and encouraging railroads to undertake a systematic and candid assessment of the hazards and resulting risks on their system.

c. Comments That the Information Protections Will Allow Railroads To Hide Safety Hazards

AAJ asserts the information protections will allow railroads to hide safety hazards. AAJ believes the threat of disclosure of these hazards creates an incentive for railroads to correct them immediately. AAJ points to multiple cases it believes prove railroads routinely hide evidence of hazards. CCAN also argues that the information protections would allow railroads to hide knowledge of safety problems and delay correcting known or suspected hazards. Labor Organizations II express a similar concern that the information protections would prevent knowledge of future risks known by railroads. Specifically, Labor Organizations II assert the information protections would hide risks uncovered by a railroad resulting from future rulemakings.

FRA disagrees. The purpose of the RRP is for railroads to identify hazards and resulting risks and to take the appropriate measures to mitigate or eliminate these hazards. Without the information protections, an RRP could result in an effort-free tool for plaintiffs in litigation against railroads, which would discourage railroads from identifying hazards and resulting risks, thus frustrating the intent behind section 20156. The RRP rule and information protections will encourage railroads to identify and address hazards. Further, if a railroad is already required by another law or regulation to collect information to show compliance with existing laws or regulations, that information will not be protected. Further, the information protections' narrow application to information that a railroad compiles or collects ''solely'' for an RRP purpose will not allow a railroad to claim that the provisions protect all information regarding risks relating to future technologies or rulemakings. Once a railroad uses such information beyond the scope of its RRP, § 271.11 will not protect the non-RRP use of the information outside the railroad's RRP. For example, if the railroad gives RRP information to a contractor to use while performing maintenance work for the railroad, § 271.11 will not extend to the contractor's use of the information. Therefore, railroads will not be able to use the RRP information protections to hide issues of non-compliance or avoid future regulatory requirements.

Several commenters also expressed concern the information protection provisions would allow railroads to hide information related to the transportation of crude oil by rail. One individual specifically commented that the RRP final rule should require railroads to provide detailed crude-by-rail information.

The information protection provisions in this final rule explicitly do not protect any information that a railroad must compile or collect ''pursuant to any other provision of law or regulation.'' This excludes from protection any crude oil information a railroad must collect under Federal law, including (but not limited to) the Enhanced Tank Car Standards and Operational Controls for High-Hazard Flammable Trains (HHFT Final Rule) that FRA and the Pipelines and Hazardous Materials Safety Administration (PHMSA) jointly issued. *See generally* 80 FR 26644–26750 (May 8, 2015). Further, because the HHFT Final Rule and other Federal regulations contain provisions requiring the provision and maintenance of certain hazardous material information, FRA does not believe that this RRP final rule should impose additional crude-by-rail information requirements. *See e.g.,* DOT's Emergency Restriction/Prohibition Order, DOT–OST–2014–0067, May 7, 2014, *available at https://www.transportation.gov/briefing-room/emergency-order.*

4. Comments That the RRP Final Rule Does Not Need To Limit the Disclosure of Evidence

AAJ contends that FRA can issue an RRP rule without limiting the discovery of evidence, just like FAA did in its Safety Management System (SMS) rulemaking.

FRA disagrees. A significant difference between the FRA and FAA programs is the scope of statutory authority Congress gave each agency to protect information collected or maintained as part of an SMS. The FAA's authority under 49 U.S.C. 44735 limits the protection of SMS voluntarily-submitted information (such as reports, data, or other information produced or collected for purposes of developing and implementing an SMS) to protection from FOIA disclosure by the FAA. Congress similarly protects risk reduction information from mandatory FOIA disclosure in section 20118. However, Congress gave FRA authority to further protect RRP information in section 20119, which directed FRA to conduct the study and authorized FRA to issue a regulation addressing the results of that study.

As discussed above, the Final Study Report concludes that it would be within FRA's authority and in the public interest for FRA to promulgate a regulation protecting certain risk analysis information held by the railroads from discovery and use in litigation. The final report also makes recommendations for the drafting and structuring of such a regulation. *See* Final Study Report at 63–64. Therefore, FRA determined the information protections in this final rule are consistent with the authority Congress provided in section 20119 and the conclusion of the Final Study Report.

ARLA also argues that railroads will honestly identify risks and mitigations without the information protections because labor unions will assure a railroad's compliance by participating

in the identification of risks and mitigations.

FRA agrees with ARLA that employee participation in the risk-based HMP is essential and will improve a railroad's RRP. FRA does not believe, however, that employee participation alone can overcome a railroad's reluctance to fully identify hazards and risks. Further, employees and labor unions may not represent the interests of the public or other accident victims. FRA therefore believes the information protections will provide important additional encouragement for a railroad to assess its hazards and risks.

5. Comments Requesting Preservation of State Tort Law Based Claims

AAJ requests that FRA specifically preserve State tort law based claims. AAJ believes that because railroads must submit their RRP plans to FRA for approval, railroads may claim they are immune from any safety hazard claim or that FRA's approval of the RRP plan preempts any State law claim. Non-profit employee labor organizations also raised this concern in response to the SSP NPRM.

To address this issue, FRA is including § 271.301(d)(4) in the final rule, which provides that approval of a railroad's RRP plan under this part does not constitute approval of the specific actions the railroad will implement under its RRP plan and shall not be construed as establishing a Federal standard regarding those specific actions. FRA will not approve the specific mitigation and elimination measures a railroad adopts to address identified hazards and risks. FRA also does not intend the RRP rule to preempt State standards of care regarding the specific risk mitigation actions a railroad will implement under its RRP plan. Accordingly, § 271.301(d)(4) clarifies that FRA approval of a railroad's RRP plan is not approval of any specific actions a railroad implements under that RRP plan, including any specific mitigation and elimination measures a railroad chooses.

6. Comments That a Judge Should Determine Information Admissibility

Labor Organizations II propose a compromise position where ''risk reduction facts would be admissible if it is determined by a judge that the information would be 'in furtherance of the highest degree of safety in railroad transportation.' '' As Labor Organizations II explain, the phrase ''in furtherance of the highest degree of safety in railroad transportation'' comes from 49 U.S.C. 103(c), which is the safety standard Congress mandated FRA to follow in its administration of railroad safety.

FRA does not believe this suggestion would improve the proposed information protections. Labor Organizations II's proposal only addresses the admission of risk reduction information into evidence and does not indicate whether discovery protections are necessary. The suggestion also does not clarify when a judge should determine whether admissibility of information is in furtherance of the highest degree of safety in railroad transportation. As such, FRA believes the suggestion would lead to the type of litigation avalanche that AAJ and ARLA fear, where courts would have to routinely interpret the meaning of ''in furtherance of the highest degree of safety in railroad transportation.'' Labor Organizations II's suggestion is therefore too imprecise to implement and would lead to an increase in costly litigation.

7. Comments Suggesting FRA Should Only Protect a Railroad's Hazard Analysis Form

One individual suggested that FRA narrowly draft the regulation to only protect a railroad's hazard analysis form from disclosure.

FRA declines to implement this individual's suggestion. The suggested approach would leave too much risk reduction information unprotected, resulting in inadequate information protections. For example, the suggested approach would not protect information a railroad might not include in the hazard analysis form, such as supporting data spreadsheets or candid discussions with employees about hazards and risks. The suggested approach also would not protect information a railroad uses to track the effectiveness of an implemented mitigation measure. Further, an effective RRP cannot lock important information in a hazard analysis form forever, as a railroad must use such information for other mandatory RRP components (such as its Safety Performance Evaluation or annual Internal Assessment).

Moreover, the suggested approach could encourage a railroad to claim protection for non-RRP information simply by placing it in a hazard analysis form. FRA believes, however, that information should be protected based on how the railroad is using the information (*e.g.,* is the railroad using the information solely for RRP purposes?), not merely on whether or not the railroad included the information in a hazard analysis form.

Finally, protecting information beyond a railroad's hazard analysis is consistent with section 20119(a), which directed FRA to study protecting RRP information in various forms, including ''any report, survey, schedule, list, or data compiled or collected'' for various RRP purposes. The final rule also does not require a railroad to use a specific hazard analysis form for its RRP, so it would be unclear which document would be the ''hazard analysis form.'' Therefore, the information protections would be applied inconsistently based on which document was considered the ''hazard analysis form.''

For these reasons, FRA declines to adopt the suggested approach.

8. Comments That the Information Protections Are Too Narrow

FRA received several comments arguing that the proposed information protections are too narrow. ASLRRA commented that FRA is not protecting data as Congress intended in the RSIA, asserting FRA improperly relied on section 409 and the Supreme Court's decision in *Guillen* because both significantly predate the RSIA. Instead, ASLRRA believes that FRA should only rely on the RSIA and protect ''any report, survey, schedule, list or data compiled or collected for the purpose of evaluating, planning or implementing a railroad safety risk reduction program . . . including a railroad carrier's analysis of its safety risks and its statement of the mitigation measures with which it will address those risks.'' According to ASLRRA, any limitations FRA imposes on this language are inappropriate.

FRA disagrees and believes it has properly limited the scope of the information protections. As explained above, FRA believes it correctly used section 409 and *Guillen* as models for the information protections. ASLRRA provided no reason, other than age, why FRA should not consider *Guillen's* analysis sound guidance for establishing RRP information protections.

FRA also believes ASLRRA mischaracterized Congress' intent in section 20119. Section 20119 does not directly establish parameters for protecting risk reduction information. Rather, it requires FRA to conduct a study and authorizes FRA to promulgate a rule addressing the results of that study. Section 20119(b) also does not mandate the scope of any information protections. FRA therefore concludes that the proposed information protections are consistent with Congress' intent in the RSIA to authorize FRA to decide the scope of the information protections.

ASLRRA also questions FRA's explanation in the NPRM preamble that the information protections would extend to the Short Line Safety Institute (Institute) only if FRA finds the Institute is part of a complete RRP program. *See* 80 FR 10964 (Feb. 27, 2015). Specifically, ASLRRA asserts there is no evidence small railroads will attempt to obtain approval for, or operate under, inadequate programs. FRA supports development of the Institute. FRA does not believe, however, it has authority under RSIA to extend information protections to programs that do not fully meet the requirements of this RRP final rule. Section 20119(a) (emphasis added) only mandated FRA (as delegated by the Secretary) to study protections for information ''compiled or collected for the purpose of evaluating, planning, or implementing a *railroad safety risk reduction program required under this chapter.*'' Under the rule, a complete RRP must contain several components, including (but not limited to) a railroad's risk-based HMP and safety performance evaluation. A railroad must also comply with the rule's requirements for RRP internal assessment and external evaluations. If the Institute either does not meet all the rule's requirements for a railroad, or is otherwise not part of a railroad's broader RRP that does meet the requirements, the Institute is neither a complete RRP nor part of a complete RRP, and the information protections may not extend to Institute information.

In a joint comment, AAR and ASLRRA (AAR/ASLRRA) commented on the NPRM's discussion in the preamble, which states § 271.11 would only protect information once FRA approves a railroad's RRP plan. They believe that approach does not make sense and would weaken the rule's protections. After reviewing the NPRM's discussion, FRA agrees with AAR/ASLRRA that the discussion in the preamble to the proposed rule does not properly reflect the scope of the information protections. *See* 80 FR 10952 (Feb. 27, 2015). In the preamble to the NPRM, FRA explained that railroads should not begin implementing an RRP plan before FRA approval, erroneously stating the information protections would not apply to information a railroad did not compile or collect for an FRA-approved RRP plan. FRA's intent was to explain that a railroad should not begin performing hazard analysis or implementing mitigation measures under its RRP plan before FRA approves the plan. However, FRA overlooked that once the information protections are in effect, but before FRA approves a railroad's RRP plan, a railroad could compile or collect information for the purpose of developing its RRP plan that should be protected. FRA therefore does not intend to limit the information protections only to information a railroad compiles or collected for an RRP plan FRA has already approved. Accordingly, § 271.11 protects information compiled or collected solely for the purpose of planning, implementing, or evaluating an RRP.

B. Other Topics

1. Transportation of Hazardous Materials

Some commenters (including Friends of the Earth, Mountain Watershed Association, and approximately four individuals) suggested that an RRP final rule should require railroads to address issues related to high-hazard flammable trains and routing of hazardous materials. One individual asserted that the RRP final rule should simply ban the transportation of Bakken crude oil, while another individual suggested constructing a tank car inspection facility on the Canadian border.

FRA shares the commenters' concerns regarding the safe transportation of large quantities of crude oil and other hazardous materials by rail, and DOT has taken numerous actions to reduce the risk to public safety and the environment posed by the movement of crude oil and other energy products by rail. A summary of those actions and more information are available online at: *https://www.phmsa.dot.gov/safe-transportation-energy-products/safe-transportation-energy-products-overview.*

DOT has also addressed the routing of hazardous materials by rail. Under 49 CFR 172.820, railroads must perform a routing analysis for HHFTs and other trains carrying certain explosives, material poisonous by inhalation, and radioactive materials. *See* § 172.820(a). At a minimum, this routing analysis must consider 27 separate safety and security factors. *See* § 172.820(d) and part 172, appendix D. FRA enforces these routing requirements under 49 CFR 209.501 and can (in consultation with PHMSA, the Transportation Security Administration, and the STB) direct a railroad to use an alternative route if the railroad's route selection documentation and underlying analysis are deficient and fail to establish that the chosen route poses the least overall safety and security risk. *See* § 209.501(a) and (d).

Because these (and other) DOT actions address hazardous materials routing and the safety of transporting crude oil by rail, FRA does not believe the RRP final rule needs to impose additional—and potentially duplicative—requirements directed at these issues. Nothing in the final rule, however, prohibits a railroad from including HHFTs and hazardous materials routing in its risk-based HMP, and many railroads may choose to do so, particularly if they find that doing so allows them to more efficiently comply with both the RRP rule and the other DOT requirements addressing hazardous materials. A railroad including HHFTs and hazardous materials routing in its risk-based HMP would still, of course, remain subject to requirements of Federal hazardous materials and rail safety laws and regulations that apply independently of this final rule. (FRA notes that the rule's information protection provisions will not apply to any hazardous materials routing or safety information a railroad must collect under another Federal law or regulation.) FRA further notes that the mitigating actions a railroad may take to reduce the risk of any accident/incident will often be the same actions a railroad would take to reduce the risk of an accident/incident resulting in a release of hazardous materials (*e.g.,* mitigating actions taken to prevent derailments). Finally, FRA's approach is consistent with the RSIA, which does not specifically require a railroad to include HHFTs and hazardous materials routing in its risk analysis. *See* 49 U.S.C. 20156(c).

2. Comments on Performance-Based Rule and Flexibility

The NPRM preamble described RRP as a performance-based rule that would provide a railroad flexibility to tailor RRP requirements to its specific operations. *See* 80 FR 10950–10951 (Feb. 27, 2015). As the NPRM preamble explains, each railroad has a unique operating system and not all railroads have the same amount of resources. *Id.* Accordingly, FRA did not propose to establish prescriptive requirements that may be appropriate for one railroad but unworkable for another. *Id.*

To clarify, the NPRM's description of RRP as a performance-based rule refers primarily to how a railroad identifies hazards and chooses strategies to mitigate risks associated with those hazards. FRA is requiring railroads to specify the performance standard (reduction in safety risk as identified in a statement defining specific, measurable goals of the RRP and describing clear strategies for reaching those goals under § 271.203(c)) but is not specifying the specific subject areas,

processes, or tools to be used by the railroads in complying with the rule. The purpose of an RRP is to reduce a railroad's accidents/incidents, injuries, and fatalities, but the railroad has flexibility to identify hazards and mitigate risks in a manner best-suited to its unique system. FRA would not, for example, require a railroad to use a specific hazard analysis tool or mandate implementation of a certain mitigation strategy to address a risk. How a railroad prepares, adopts, and implements an RRP, however, is subject to minimum Federal standards, in that a railroad must support its RRP with an RRP plan that contains certain components, follow the provisions of that RRP plan, and ensure that it conducts an internal assessment of its RRP. In short, requirements for an RRP's substance are performance-based, but an RRP's process must meet certain minimum Federal standards.

Several commenters supported FRA's decision to propose a performance-based, flexible RRP rule. AAR/ASLRRA acknowledged the performance-based nature of RRP, while Amtrak commented that the final rule ''needs to be performance based and flexible. It should provide the opportunity for new creative programs rather than a prescriptive checklist of requirements or conditions.'' DNV–GL also noted the NPRM was ''to a large extent aligned with good risk management practice in potentially hazardous industries[,] particularly those that have learned the lessons of previous accidents and implemented performance-based regimes of safety regulation.''

Labor Organizations I and several non-profit organizations and individuals expressed concern that FRA described RRP as a performance-based, flexible rule. Public Citizen Texas, for example, commented that the proposed flexibility did not comply with the RSIA mandate.

The nature of SMS demands a performance-based, flexible RRP rule. Not every railroad will have the same hazards and risks, and different railroads may find different mitigation strategies equally effective for certain risks. Additionally, FRA notes that the RRP final rule reflects every RSIA requirement (except for the portions of the RSIA mandate the SSP final rule addresses and the FMP rulemaking will address). FRA therefore believes that establishing an RRP final rule that is performance-based and flexible reflects the outcome-oriented nature of SMS and meets the RSIA mandate.

Regarding Labor Organizations I's specific comment, FRA clarifies in this preamble that both the RRP and SSP rule provide railroads flexibility to tailor an RRP or SSP to a railroad's particular operations. Like the SSP rule, the RRP rule depends on a railroad's ability to thoroughly and candidly assess its unique hazards and risks, not the railroad's ability to meet certain prescriptive requirements. Rather, RRP requires a railroad to engage in self-analysis that a railroad will conduct in conjunction with the railroad's directly affected employees and FRA oversight. Since no two railroads' operations are exactly the same, no two RRPs will be exactly the same. Further, regardless of the amount of flexibility the RRP rule affords railroads, the directly affected employees, including Labor Organizations I, will have an opportunity to provide input and work with the railroads on the development of the RRP plan. FRA also added provisions to the final rule clarifying that a railroad must involve its employees in the RRP. The section-by-section analysis will specifically discuss these provisions further.

3. Comments on Streamlined Safety Management System (SMS)

The NPRM preamble also described the proposed RRP rule as a streamlined version of an SMS, explaining that FRA had not included a number of components common to SMS to closely adhere to the RSIA mandate. *See* 80 FR 10959 (Feb. 27, 2015). The NPRM preamble specifically identified the following components that FRA did not propose: (1) Processes ensuring that safety concerns are addressed during the procurement process; (2) development and implementation of processes to manage emergencies; (3) processes and procedures for a railroad to manage changes that have a significant effect on railroad safety; (4) processes and permissions for making configuration changes to a railroad; and (5) safety certification prior to the initiation of operations or implementation of major projects. *See* 80 FR 10959 (Feb. 27, 2015).

Generally, the non-profit organizations and individuals who expressed concern about the flexibility of the proposed RRP rule also questioned FRA's description of RRP as streamlined and asserted that the proposed RRP rule was less rigorous than the RSIA mandate, which requires a ''comprehensive and systematic'' safety management system. DNV–GL shared the concerns of these commenters, arguing that every element of a safety management system is important and that ''it is better to have a basic program in place for every element than to be excellent in some and have no program in others.'' Labor Organizations I also asked to better understand why FRA was not requiring the additional components, arguing that they would expect an RRP to contain the ''proven safety systems such as the items FRA identifies.''

FRA disagrees with the commenters that the proposed rule does not comply with the RSIA mandate (except for the portions of the RSIA mandate the SSP final rule addresses and the FMP rulemaking will address). As the NPRM explained, FRA proposed a streamlined version of a safety management system ''to adhere as closely as possible to the requirements of the RSIA.'' *Id.* The RSIA does not mandate a full SMS [14] but requires railroad RRPs to contain certain components, each of which the RRP final rule also contains (as supplemented by the SSP and FMP rulemakings). The RRP final rule adequately addresses railroad safety hazards by following the RSIA mandate, particularly as the core of the program is a systematic risk-based hazard management program that includes a risk-based hazard analysis.

4. Comments on Plan Approval

The NPRM preamble stated FRA would only approve the processes and procedures in a railroad's RRP plan, not the entire RRP. *See* 80 FR 10977 (Feb. 27, 2015). FRA will not, for example, approve specific mitigation measures in a railroad's RRP plan. FRA received several comments from individuals and non-profit organizations urging FRA to approve entire RRPs, not just RRP plans. These commenters were concerned FRA's decision to only approve RRP plans represented a diminished role for FRA implementation and oversight of RRPs and did not comply with the RSIA mandate.

FRA disagrees and believes its decision to approve only RRP plans satisfies the RSIA mandate. Section 20156(a)(3) directs FRA to ''review and approve or disapprove railroad safety risk reduction program *plans* within a reasonable period of time.'' (Emphasis added.) Further, an RRP is an ongoing program that supports continuous safety improvement. As discussed in the NPRM, ''a railroad that conducts a one-time risk-based hazard analysis and does nothing further after addressing the

[14] The NPRM explained that a full SMS would contain numerous components FRA was not proposing to mandate in the RRP rule, such as a description of the railroad management and organizational structure (including charts or other visual representations) or a description of the processes and procedures used for maintenance and repair of infrastructure and equipment, rules compliance and procedures review, workplace safety, workplace safety assurance, or public safety outreach. *Id.*

results of that analysis will not have established a compliant RRP.'' 80 FR at 10969 (Feb. 27, 2015). An RRP is not a one-time exercise. As such, FRA does not believe it is possible to meaningfully approve a railroad's entire RRP, because an RRP should be continuously moving forward and improving. If FRA approved a railroad's program, it would require a railroad to freeze an RRP at the moment of approval. That position is not consistent with the dynamic and changing nature of a successful RRP. FRA therefore is not changing the final rule to require FRA approval of a railroad's RRP.

5. Comments on Fatigue Management Plans

The RSIA requires an RRP to include an FMP meeting certain requirements. The RRP NPRM did not address this mandate because FRA, with the assistance of industry stakeholders, is implementing it through the separate FMP rulemaking process.

Labor Organizations I commented that FRA was violating the RSIA mandate by failing to require FMPs in the proposed rule text and that ''the proposal of the FRA to provide an unknown number of years of additional delay is the functional equivalent of an open-ended waiver.'' Labor Organizations I also commented that RSIA section 108 required FRA to promulgate a fatigue rulemaking no later than October 2011.

FRA notes that RSIA section 108 applies specifically to hours-of-service reform, not the fatigue management programs that RSIA section 103 mandates for RRP. *See* 49 U.S.C. 20156(f). As such, arguments based on RSIA section 108 are inapplicable to FMPs. Nevertheless, FRA is working to issue a proposed FMP rulemaking. As the NPRM discussed, the RSAC voted to establish the FMP Working Group to address the FMP mandate in December 2011. The FMP Working Group completed its work in September 2013 and submitted its recommendations to FRA. FRA is considering these recommendations as it develops an FMP rulemaking. Ultimately, any fatigue management plans that FRA requires pursuant to section 20156(d)(2) and (f) would be part of a railroad's overall RRP. FRA does not believe that it is failing to meet the RSIA mandate by addressing the FMP requirements in a separate rulemaking process with stakeholder assistance. The SSP final rule takes the same approach and does not include FMP requirements. *See* 81 FR 53856–53857 (Aug. 12, 2016).

6. Comments on the RSAC Process

FRA received comments from several individuals arguing that the RSAC RRP Working Group process was flawed because it did not include an industry risk reduction analysis expert. One commenter specifically noted the RSAC process did not include participation from those in high-risk industries, including chemical shipping industries, universities, and consultants. These commenters suggested that FRA should reopen the comment period and reconsider the proposed rule based on much more information from the at-risk public and public officials and from experts on industrial SMS.

FRA declines to reopen the comment period again for several reasons. First, FRA representatives who have participated in the APTA system safety program have significant experience with industry risk reduction programs, as explained in the SSP NPRM. *See* 77 FR 55375 (Sept. 7, 2012). Railroad representatives who participated in the RSAC process also brought to the process experience with risk reduction programs. Overall, the RRP Working Group included a number of certified safety professionals, certified industrial hygienists, system safety managers, and safety directors. FRA therefore concludes that the RSAC RRP Working Group included ample expertise in the area of industry risk reduction analysis.

Second, FRA has provided the public—including public officials, private individuals, and experts on industrial SMS—ample notice and opportunity to participate in the RRP rulemaking process. The RSIA mandate first notified the public FRA must require certain railroads to implement railroad safety risk reduction programs. The Regulatory Plan and Unified Agenda of Regulatory and Deregulatory Actions (published by the Regulatory Information Service Center and made available to the public at *www.Reginfo.gov*) have also included the risk reduction rulemaking since the fall of 2009. *See http://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPubId=200910&showStage=active&agencyCd=2100&Image58.x=35&Image58.y=17.*

The ANPRM also solicited public comment on how FRA could best develop and implement a risk reduction regulation based on the RSIA requirements. *See* 75 FR 76345–76351 (Dec. 8, 2010). Interested persons could submit comments to the ANPRM. FRA received 12 written comments in response to the ANPRM from a variety of entities, including railroads, industry organizations, non-profit employee labor organizations, a consulting firm, and a private citizen. The RSAC subsequently discussed in depth many of the questions and issues these comments raised.

After it published the ANPRM and the comment period closed, FRA also held two public hearings (announced in the **Federal Register**) giving interested persons an additional opportunity to present oral statements and to offer information and views on development of a risk reduction regulation in response to the ANPRM. *See* 76 FR 40320 (July 8, 2011). As with the ANPRM, the hearing testimony focused on topics the RSAC RRP Working Group continued to discuss. As noted above, FRA also held a public hearing and reopened the comment period on several occasions following the publication of the NPRM. The RSAC RRP Working Group also met to review and discuss comments received in response to the NPRM and the public hearing.

Overall, FRA concludes reopening the RRP NPRM for further consideration and comment is not necessary because the RSAC RRP Working Group contained sufficient expertise in risk reduction and because FRA provided interested risk reduction experts numerous opportunities to participate in the rulemaking process.

7. Comments on the Relationship Between RRP and SSP

FRA explained in the NPRM preamble that it worked with both the RSAC RRP Working Group and the RSAC System Safety Task Group on language implementing the RSIA mandate on information protection and consultation process requirements, with the understanding the RRP and SSP NPRMs would include the same language on both issues for review and comment. *See* 80 FR 10955 (Feb. 27, 2015). As such, the RRP NPRM did not respond to comments that FRA received in response to the SSP NPRM, but explained that FRA would consider comments responding to both NPRMs when developing the RRP final rule. *See* 80 FR 10958–10959 (Feb. 27, 2015).

Labor Organizations I objected to FRA's position, arguing that FRA had a duty to address comments on the SSP NPRM in the RRP NPRM. FRA disagrees. SSP and RRP are separate rulemakings that apply to different entities. FRA concluded, therefore, that it would be fair to allow Class I railroads and potential ISP railroads the same opportunity to respond to the proposed information protections and

consultation process requirements that the passenger railroads had in responding to the SSP NPRM. Moreover, because this final rule contains the same information protection provision as the SSP final rule, it incorporates FRA's response to all comments received on the matter in both the SSP and RRP rulemakings.

8. Comments on the Short Line Safety Institute

ASLRRA commented that small railroad participation in the Short Line Safety Institute (Institute) should suffice as complete compliance with the requirements in the NPRM. According to ASLRRA, the Institute assessment process is a comprehensive review of safety practices and culture, which it believes is consistent with the intent of an RRP. ASLRRA acknowledges that a key component of an effective RRP is performance of a risk assessment and claims the Institute has teams of assessors specifically trained (using FRA-approved materials) in a well-documented safety assessment process. ASLRRA also claims FRA would fulfill the Small Business Regulatory Enforcement Fairness Act (SBREFA) requirement to grant special considerations to small businesses by accepting participation in the Institute as satisfying RRP requirements. In response to DOT's request for public comments on its regulatory review initiative, ASLRRA similarly commented that FRA should utilize the Institute to work with short line railroads as the mechanism for risk reduction within the short line industry and not place unnecessary and burdensome regulations on short lines. *See* 82 FR 45750–45753 (Oct. 2, 2017) and DOT–OST–2017–0069–2666. The following discussion is FRA's response to ASLRRA's comments discussing the Institute for both the NPRM and DOT's regulatory reform initiative.

FRA supports the development of the Institute to promote the safety of short line and regional railroad operations. However, for Institute participation to constitute an RRP, the Institute would have to fully comply with each RRP requirement this final rule establishes, which are consistent with the RSIA requirements. FRA currently cannot determine whether the Institute will fully comply with the RSIA mandate or the requirements of this final rule. For example, FRA cannot determine whether the Institute will include certain mandated components, such as an RRP plan reviewed and approved by FRA, consultation with directly affected employees on the contents of an RRP plan, annual internal assessments, and a technology implementation plan. Rather, FRA believes it is more appropriate to make this determination when reviewing RRP plans under § 271.301 of the final rule.

Further, FRA does not believe it has to accept the Institute as a fully-compliant RRP to comply with SBREFA or otherwise avoid placing unnecessary and burdensome regulations on short line and regional railroads. Because an RRP is scalable by design, a short line or regional railroad's full compliance with an RRP final rule is not likely to be as complex and comprehensive as it would be for a larger railroad. The rule will therefore not unduly burden short line and regional railroads. The Final Regulatory Flexibility Analysis in Section VII.B further discusses how FRA has considered small business concerns in developing the RRP final rule.

9. Comments on Other SMS Programs

As both the NPRM and this preamble discuss, other Federal agencies have established or proposed SMS requirements, and SMS programs have developed to assure high safety performance in various industries, including aviation, passenger railroads, the nuclear industry, and other industries with the potential for catastrophic accidents. FRA received several comments urging FRA to consider other such SMS programs as both positive and negative models for RRP.

Transport Action Canada (TAC) commented that the effect of SMS in the Canadian railroad industry has not been positive. Specifically, TAC expressed concern that SMS-type programs such as RRP are ''incapable of assuming . . . the role of government in ensuring public safety.''

FRA does not believe this RRP rule will result in FRA abdicating its role ensuring railroad safety, as any alleged weakness of SMS programs in Canada does not mean SMS programs in the United States cannot be successful. The United States' railroad safety laws and regulations are different than Canada's, and the RRP rule will not replace or modify any of FRA's railroad safety regulations, responsibilities, or enforcement tools. An RRP will supplement FRA oversight of railroad safety, not replace it.

Various commenters suggested other SMS programs as models for RRP, such as the United States Environmental Protection Agency's (EPA) Risk Management Program, the Moving Ahead for Progress in the 21st Century Act (MAP–21) and the Federal Transit Administration (FTA) approach, and the Massachusetts Toxics Use Reduction Act (TURA). FRA notes that some of these SMS programs operate very differently from the way FRA exercises its railroad safety authority. For example, States have primary responsibility for enforcing SMS programs under MAP–21 through the State Safety Oversight (SSO) Program. *See* State Safety Oversight (SSO) Program, *available at http://www.fta.dot.gov/tso_15863.html* (''The SSO program is administered by eligible States with rail transit systems in their jurisdiction. FTA provides Federal funds through the SSO Formula Grant Program for eligible States to develop or carry out their SSO programs. Under 49 U.S.C. Section 5329(e), as amended by [MAP–21], FTA is required to certify each State's program to ensure compliance with MAP–21.''). Further, as FRA has already stressed elsewhere, this final rule hews closely to the RSIA mandate. If FRA used other SMS programs as a model for RRP, rather than the RSIA requirements, this could cause FRA to either fail to meet or exceed the limits of RSIA's statutory mandate.

VI. Section-by-Section Analysis

FRA is adding a new part 271 to chapter 49 of the CFR. This part satisfies the RSIA requirements for safety risk reduction programs for Class I railroads and railroads with inadequate safety performance. *See* 49 U.S.C. 20156(a)(1). This part also protects certain information compiled or collected for a safety risk reduction program from admission into evidence or discovery during court proceedings for damages. *See* 49 U.S.C. 20119.

Subpart A—General

Subpart A of the final rule contains general provisions (including a formal statement of the rule's purpose and scope) and provisions limiting the discovery and admissibility of certain RRP information.

Section 271.1—Purpose and Scope

Section 271.1 explains the rule's purpose and scope. Paragraph (a) states the purpose of this part is to improve railroad safety through structured, proactive processes and procedures developed and implemented by railroads. Paragraph (a) also states this rule requires each affected railroad to establish an RRP that systematically evaluates railroad safety hazards on its system and manages the risks generated by those hazards to reduce the number and rates of railroad accidents/incidents, injuries, and fatalities. Except for replacing the phrase ''in order to''

with ''to'' for the purpose of streamlining the regulatory language, FRA has not changed paragraph (a) from the NPRM. As the NPRM explained, the rule does not require an RRP to address every safety hazard on a railroad's system. For example, rather than identifying every safety hazard on its system, a large railroad could take a more focused and project-specific view of safety hazard identification. *See* 80 FR 10959 (Feb. 27, 2015).

An individual commenter suggested FRA's RRP rule should use an ''All-Hazards'' approach. FRA declines to adopt this suggestion because the RSIA requires an RRP to address only ''railroad safety risks'' and § 271.1(a) of the final rule accurately reflects this mandate by requiring RRPs to ''systematically evaluate railroad safety hazards.'' The RSIA does not authorize RRPs that address hazards other than railroad safety hazards.

Paragraph (b) states that this part prescribes minimum Federal safety standards for the preparation, adoption, and implementation of RRPs. A railroad is not restricted from adopting and enforcing additional or more stringent requirements that are not inconsistent with the rule. FRA did not receive any comments on this paragraph and adopts it as proposed.

Paragraph (c) states that the rule protects information a railroad compiles or collects solely for the purpose of planning, implementing, or evaluating an RRP. While paragraph (c) in the proposed rule specified that the rule would protect information ''generated'' solely for developing, implementing, or evaluating an RRP, FRA has replaced the term ''generated'' with the phrase ''compiles or collects'' to promote consistency with § 271.11. FRA has also replaced the term ''developing'' with the term ''planning'' from § 271.11. FRA made these changes only to improve clarity and consistency between this section and § 271.11 and not to make any substantive change in this part's information protections.

Paragraph (d) explains the final rule does not require an RRP to address hazards completely unrelated to railroad safety and that fall under the exclusive jurisdiction of another Federal agency. For example, an RRP is not required to address environmental hazards that would fall under the exclusive jurisdiction of the United States Environmental Protection Agency (EPA) or workplace safety hazards that would fall under the exclusive jurisdiction of the United States Department of Labor's Occupational Safety and Health Administration (OSHA). Paragraph (d) also explains an RRP should not address the safety of employees while performing inspections, tests, and maintenance. The only exception is where FRA has exercised its jurisdiction over the safety issue, as in 49 CFR part 218, subpart B, which establishes blue signal protection for workers. FRA will not approve any specific portion of an RRP plan that addresses hazards related to a safety issue that falls under the exclusive jurisdiction of another Federal agency unless FRA has exercised its jurisdiction over the safety issue.

Paragraph (d) of the NPRM proposed the same language regarding working conditions, but did not include the first sentence discussing hazards completely unrelated to railroad safety and that fall under the exclusive jurisdiction of another Federal agency. *See* 80 FR 10959 (Feb. 27, 2015). The NPRM preamble explained that while FRA is always concerned with the safety of railroad employees performing their duties, employee safety in maintenance and servicing areas generally falls under OSHA's jurisdiction. *Id.* The NPRM similarly explained that FRA did not intend RRPs to address environmental hazards and risks unrelated to railroad safety that fall under EPA's jurisdiction. *Id.* For example, the NPRM stated FRA would not expect a railroad's RRP to address environmental hazards regarding particulate emissions from locomotives that otherwise comply with FRA's safety regulations. *Id.*

AAR/ASLRRA commented the language in proposed paragraph (d) did not achieve clarification and specifically suggested FRA clarify its intent by precisely stating that the scope of an RRP does not include matters within OSHA's jurisdiction. AAR/ASLRRA also stated paragraph (d) did not address environmental issues under EPA jurisdiction.

To address AAR/ASLRRA's concern regarding EPA's jurisdiction, FRA changed paragraph (d) in the final rule to add the first sentence plainly stating that an RRP is not required to address hazards completely unrelated to railroad safety and that fall under the exclusive jurisdiction of another Federal agency. The purpose of this language is to incorporate the NPRM's explanation that an RRP should not address hazards that fall exclusively under the jurisdiction of another Federal agency, such as EPA.

FRA has otherwise not changed the proposed text of paragraph (d) that relates to working conditions, as similar language appears in the SSP final rule and FRA's regulations on passenger equipment safety standards.[15] *See* §§ 270.103(g)(4) and 238.107(c). The purpose of the language is to make clear that FRA neither intends to displace OSHA jurisdiction with respect to employee working conditions generally nor specifically with respect to the maintenance, repair, and inspection of infrastructure and equipment directly affecting railroad safety. FRA does not intend to approve any specific portion of an RRP plan that relates exclusively to employee working conditions covered by OSHA. The term ''approve'' is used to make clear that any part of an RRP plan that relates to employee working conditions exclusively covered by OSHA will not be approved even if the overall plan is approved. Additionally, the term ''specific'' reinforces that the particular portion of the plan that relates to employee working conditions exclusively covered by OSHA will not be approved; however, the rest of the plan may still be approved. If there is any confusion whether an RRP plan covers an OSHA-regulated area, FRA is available to provide assistance. The preamble to the SSP final rule contains this same explanation regarding SSP plans and working conditions exclusively covered by OSHA. *See* 81 FR 53871 (Aug. 12, 2016).

Overall, FRA's intent behind paragraph (d) in the NPRM and this final rule has not changed, and FRA has changed the language solely to address AAR/ASLRRA's concerns regarding clarity. The NPRM discussion of paragraph (d) therefore remains applicable to paragraph (d) in this final rule. *See* 80 FR 10959 (Feb. 27, 2015).

Section 271.3—Application

This section sets forth application of the rule. Except for additional language in paragraph (c), this section is the same as in the NPRM. Thus, FRA is not repeating the NPRM section-by-section analysis for paragraphs (a) and (b) in this final rule, but refers interested readers to the NPRM. *See* 80 FR 10959–10960 (Feb. 27, 2017). FRA is, however, discussing comments it received

[15] While §§ 270.103(g)(4) and 238.107(c) contain reference to working conditions ''as set forth in the plan,'' the RRP final rule does not contain this language because an RRP plan is not required to specifically address working conditions that arise in the course of conducting maintenance, repair, and inspection of infrastructure and equipment directly affecting railroad safety. FRA is also leaving the reference to FRA regulations on blue signal protection, which does not appear in the corresponding SSP language, to improve clarity. FRA does not intend this difference to indicate any substantive difference between the SSP and RRP language, as the preamble to the SSP final rule contains the same example regarding blue signal protection. *See* 81 FR 53870 (Aug. 12, 2016).

regarding tourist railroads and Class II and Class III railroads in response to the NPRM.

Paragraph (b)(2) of the NPRM proposed that the rule would not apply to tourist, scenic, historic, or excursion operations, whether on or off the general railroad system of transportation. *See* 80 FR 10989 (Feb. 27, 2015). The NPRM specifically requested public comment on how an RRP final rule should address tourist operations that may create hazards for freight operations. In response, Labor Organizations I responded that FRA should require all railroads to account for tourist operations on their lines in performing the self-critical analysis and include such operations in the railroad's RRP. FRA agrees with Labor Organizations I that a railroad required to comply with this rule must account for tourist operations on its system. FRA has made changes responding to this comment in § 271.101(d), which requires railroads to identify tourist operations that operate over the railroad's track (even if the tourist railroad is exempt from this rule) and to ensure the tourist railroad supports and participates in the railroad's RRP. The section-by-section analysis for § 271.101(d) discusses these changes further.

In this final rule, FRA added a paragraph (c) that includes language from the SSP final rule. *See* § 270.107(a)(2). This language clarifies that if a railroad contracts out significant portions of its operations, the contractor and the contractor's employees performing the railroad's operations are considered directly affected employees for this rule's purposes, including the consultation process and employee involvement requirements in §§ 271.113 and 271.207, discussed below. This language is necessary to address how directly affected employee consultation and involvement will be handled when a railroad contracts out significant portions of its operations to other entities. Contractors and contractor employees will only be considered directly affected employees when the contracts are ongoing and involve significant aspects of the railroad's operations. For example, if a railroad contracts out maintenance of its locomotive and rail cars to another entity, it is vital for the employees who are performing this maintenance to be involved in that railroad's RRP and have the opportunity to provide their valuable input on the RRP plan. Another example would be if a railroad contracts out the actual operations of its railroad to another entity. In such cases, the contracted entity and its employees operating trains on behalf of the railroad would certainly need to be part of the consultation process and otherwise involved in the railroad's RRP. If a railroad is unsure whether a contracted entity and its employees are directly affected employees for purposes of this part, FRA encourages the railroad and other interested stakeholders to contact FRA for guidance.

The Association of Tourist Railroads and Railway Museums (ATRRM) commented it supported FRA's proposed approach for tourist railroads. ATRRM commented an RRP was poorly suited to a small tourist railroad, but agreed with FRA's approach to tourist railroads that conduct their own freight operations, or which operate on RRP host railroads. ATRRM correctly understood FRA's position, and the changes made in § 271.101(d) are consistent with this position.

FRA received approximately four comments from individuals arguing that FRA should expand the scope of the RRP final rule to Class II and Class III railroads. FRA declines to incorporate this recommendation for two principle reasons. First, applying the RRP final rule to Class II and Class III railroads would go beyond the RSIA mandate and increase the number of RRP plans submitted for FRA review. FRA would therefore need more time to review all submitted plans, as well as more time to conduct external reviews of RRPs. This would divert FRA resources away from Class I railroads, which have more complex operations than Class II and Class III railroads, and ISP railroads, which FRA will have determined demonstrate inadequate safety. Adhering to the RSIA mandate, which only directs FRA to require compliance from Class I railroads, passenger railroads, and railroads with inadequate safety performance, therefore represents the best and most efficient use of FRA resources. Second, the methodology for identifying railroads with inadequate safety performance will require certain Class II and Class III railroads to comply with the RRP rule. FRA also notes that Class II and III freight railroads may voluntarily comply with the final rule.

Section 271.5—Definitions

This section contains definitions clarifying the meaning of important terms used in the rule. FRA worded the definitions carefully to minimize potential misinterpretation of the rule. Commenters on the NPRM did not have significant issues with the proposed definitions, except for a few comments FRA received on the proposed definitions of ''hazard'' and ''safety culture,'' discussed below. FRA also made changes discussed below to the definitions of ''accident/incident'' and ''pilot project.'' For definitions that did not receive any comment and have not been changed, FRA is not repeating the NPRM's section-by-section analysis in this final rule but refers interested readers to the NPRM's discussion. *See* 80 FR 10960–10962 (Feb. 27, 2015).

The NPRM preamble stated FRA was proposing an ''accident/incident'' definition identical to the definition contained in FRA's accident/incident reporting regulations at 49 CFR part 225. *See* 80 FR 10960 (Feb. 27, 2015). However, the proposed definition did not match the part 225 definition exactly, because it did not include occupational illnesses. *See* 49 CFR 225.5. This inconsistency was merely an oversight. To correct this inconsistency and to ensure future conformity with the part 225 definition and any amendments thereto, FRA has changed the final rule's definition to simply cross-reference the part 225 definition.

The NPRM proposed to define ''hazard'' as any real or potential condition that can cause injury, illness, or death; damage to or loss of a system, equipment, or property; or damage to the environment. *See* 80 FR 10989 (Feb. 27, 2015). In response, AAR/ASLRRA commented the definition of hazard did not help clarify the proposed jurisdiction statement in § 271.1(d). AAR/ASLRRA also claimed the definition places conditions that do not impact human safety or property damage squarely within the definition of hazard. As discussed above, FRA has made changes to § 271.1(d) to clarify an RRP does not have to address safety issues that are completely unrelated to railroad safety and that fall under the exclusive jurisdiction of another Federal agency, such as EPA. This does not mean, however, an RRP should not address railroad safety hazards that could result in damage to the environment, such as a derailment that could result in a hazardous materials release. *See also* 80 FR 10959 (Feb. 27, 2015). As § 271.1(a) provides, an RRP is required to address ''railroad safety hazards.'' The final rule adopts the NPRM's definition for ''hazard'' unchanged.

The NPRM proposed to define ''pilot project'' as a limited scope project used to determine whether quantitative proof suggests that a particular system or mitigation strategy has potential to succeed on a full-scale basis. *See* 80 FR 10989–10990 (Feb. 27, 2015). FRA modified this definition to replace the word ''proof'' with the phrase ''evaluation and analysis.'' FRA made this change to avoid implying that a

railroad had to meet an established quantitative threshold as proof that a pilot project has potential to succeed. FRA did not intend to establish a quantitative proof threshold, and believes ''evaluation and analysis'' more accurately describes the purpose of a pilot project. FRA also modified this definition slightly by changing ''potential to succeed on a full-scale basis'' to ''potential for full-scale success.'' The purpose of this change is only to streamline the language, and FRA does not intend any substantive change.

The NPRM proposed defining ''safety culture'' as the shared values, actions, and behaviors that demonstrate a commitment to safety over competing goals and demands. This definition is the same in the final rule and was also included in the SSP rule. *See* § 270.5 and 81 FR 53863–53864 (Aug. 12, 2016). As the NPRM explained, FRA based the definition on a research paper published by the DOT Safety Council. *See* 80 FR 10962 (Feb. 27, 2015). The DOT Safety Council developed this definition after extensive review of definitions used in a wide range of industries and organizations over the past two decades. *Id. See also* U.S. Dep't of Transp., John A. Volpe Nat'l Transp. Sys. Ctr., ''Safety Culture: A Significant Influence on Safety in Transportation,'' 2–3 (2017), *available at https://www.fra.dot.gov/eLib/details/L18784#p1_z50_gD_ksafety%20culture.* The NPRM also acknowledged the proposed definition was different than the definition that the RRP Working Group recommended. Specifically, FRA noted that some participants during RRP Working Group discussion expressed concern that the language ''over competing goals and demands'' would require a railroad to make safety the ultimate priority to the exclusion of all other concerns, without providing flexibility for a railroad to balance the concerns of profit and efficiency. The NPRM explained FRA selected the proposed definition because it was important to use a definition the DOT Safety Council formulated. *See* 80 FR 10962 (Feb. 27, 2015). The definition also would not require a railroad to prioritize absolute safety over competing goals and demands (*i.e.,* it would not require a railroad to have a perfect safety culture). Rather, FRA explained that the proposed definition merely expressed how a railroad should evaluate safety culture by measuring the extent to which a railroad emphasizes safety over competing goals and demands. *Id.*

AAR/ASLRRA responded to this discussion by commenting there was no doubt that the proposed definition requires ''a commitment to safety over competing goals and demands,'' because that is what the definition says. AAR/ASLRRA further suggested that if FRA's intent was to measure the extent to which a railroad emphasizes safety over competing goals and demands, that language should be included. FRA declines to change the proposed ''safety culture'' definition as suggested because doing so would eliminate the benefits of having a general definition the DOT Safety Council developed and approved. There is value in establishing a shared understanding of safety culture that can be applied across many contexts, and developing a common understanding of the elements that comprise a strong safety culture can help DOT agencies have a better basis for improving safety programs, policies, and strategies. *See* U.S. Dep't of Transp., John A. Volpe Nat'l Transp. Sys. Ctr., ''Safety Culture: A Significant Influence on Safety in Transportation,'' 2 (2017), *available at https://www.fra.dot.gov/eLib/details/L18784#p1_z50_gD_ksafety%20culture.* As explained in the NPRM, FRA also disagrees with AAR/ASLRRA and believes the definition does not require railroads to ''absolutely and necessarily'' demonstrate a commitment to safety over competing goals and demands but only describe how certain shared values, actions, and behaviors demonstrate such a commitment. Rather, the rule requires that a railroad design its RRP to promote and support a positive safety culture (§ 271.101(a)), develop processes for identifying and analyzing its safety culture (§ 271.105(a)), and include in its RRP plan a statement describing the railroad's safety culture and how it promotes improvements to its safety culture (§ 271.203(b)(1) and (2)).[16] FRA believes these provisions generally require a railroad to define its own safety culture and develop processes for analyzing and improving it. Nowhere does the RRP final rule require a railroad to establish a safety culture that absolutely prioritizes safety. For these reasons, FRA believes the definition for safety culture is appropriate.

Section 271.7—Reserved

The NPRM proposed to include a provision on waivers in § 271.7, explaining that 49 CFR part 211 generally contains rules governing the FRA waiver process. *See* 80 FR 10990 (Feb. 27, 2015). ASLRRA commented suggesting that ''it is best to have a single waiver rule to reduce confusion and increase familiarity with proper waiver procedures.'' FRA agrees with ASLRRA on this issue and finds that the NPRM's proposed provision on waivers is unnecessary because part 211 already contains the rules governing the FRA waiver process. The provision would have therefore served only as a cross-reference to part 211 and not have had any independent legal effect. The SSP final rule also does not contain its own provision on waivers. *See* 81 FR 53864 (Aug. 12, 2016). FRA has therefore not included a provision on waivers in this RRP final rule although FRA is reserving this section in case FRA decides to add such a provision in the future.

Section 271.9—Penalties and Responsibility for Compliance

This section contains provisions regarding penalties and the responsibility for compliance. Except for the change discussed below, FRA adopts this section from the NPRM unchanged. Therefore, FRA refers interested readers to the NPRM discussion. *See* 80 FR 10962 (Feb. 27, 2015).

This section in the NPRM proposed a civil penalty of at least $650 and not more than $25,000 per violation, except for a penalty not to exceed $105,000 that may be assessed for a grossly negligent violation or a pattern of repeated violations has created an imminent hazard of death or injury to individuals, or has caused death or injury. *Id.* Since the NPRM was published in 2015, DOT has issued a final rule, in accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIAA), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act),[17] that provides the 2018 inflation adjustment to civil penalty amounts that may be imposed for violations of certain DOT regulations. *See* 83 FR 60732 (Nov. 27, 2018). To avoid the need to update this section every time the civil penalty amounts are adjusted for inflation, FRA has changed this section by replacing references to specific penalty amounts with general references to the minimum civil monetary penalty, ordinary maximum civil monetary penalty, and aggravated maximum civil monetary penalty. FRA has also added language to

[16] The SSP rule contains similar requirements related to safety culture. *See* § 271.101(b) (''A railroad's system safety program shall be designed so that it promotes and supports a positive safety culture at the railroad.''), § 271.103(b) (''This policy statement shall . . . [d]escribe the . . . safety culture of the railroad''), and § 271.103(t) (''A railroad shall set forth a statement in its SSP plan that describes how it measures the success of its safety culture. . . .'').

[17] The FCPIAA and the 2015 Act require federal agencies to adjust minimum and maximum civil penalty amounts for inflation to preserve their deterrent impact. *See* 83 FR 60732 (Nov. 27, 2018).

this section referring readers to 49 CFR part 209, appendix A, where FRA will continue to specify statutorily provided civil penalty amounts updated for inflation.

While this section in the NPRM noted the final rule would include a schedule of civil penalties, FRA has decided to provide such a schedule on its website instead of as an appendix to the final rule. FRA therefore changed the final sentence of paragraph (a) in this section to direct readers to the FRA's website for a schedule of civil penalties.

This penalty schedule will reflect the requirements of the final rule. Because such penalty schedules are statements of agency policy, notice and comment are not required before their issuance, and FRA did not propose a penalty schedule in the NPRM. *See* 5 U.S.C. 553(b)(3)(A). Nevertheless, FRA invited comment on what a final penalty schedule should contain. *See* 80 FR 10978 (Feb. 27, 2015). However, FRA did not receive any comments other than Labor Organizations I's comment the NPRM did not include a proposed penalty for violation of the § 271.207 requirements to consult with directly affected railroad employees using good faith and best efforts. The penalty schedule on FRA's website will include guideline penalty amounts for violations of various requirements in § 271.207.

Section 271.11—Discovery and Admission as Evidence of Certain Information

As discussed in the Statutory Background (Section IV.D), the Final Study Report concluded that it is in the public interest to protect certain information generated by railroads from discovery or admission into evidence in litigation. Section 20119(b) provides FRA the authority to promulgate a regulation if FRA determines that it is in the public interest, including public safety and the legal rights of persons injured in railroad accidents, to prescribe a rule addressing the results of the Study.

This section establishes protections based on the Final Study Report for information a railroad compiles or collects solely for RRP purposes in Federal or State court proceedings for damages involving personal injury, wrongful death, or property damage. These protections are narrow and apply only to information generated solely for a railroad's RRP, aiming to ensure that a litigant will not be better or worse off than if the protections had never existed. FRA intends these protections to be strictly construed.

In Sections IV.D and V.A of this preamble's discussion, FRA explains the statutory background of this section, general comments on the NPRM's proposed information protections, and FRA's response to those comments. This section-by-section analysis will not revisit the general issues and comments FRA discussed above, but will focus on responding to specific comments on the proposed rule text and explaining the final rule. The language of this section is also substantively identical to the language promulgated by the SSP final rule in § 270.105. *See* 81 FR 53900 (Aug. 12, 2016). The preamble to the SSP final rule contains a significant discussion on the protections' background. *Id.* at 53878–53879.

Under § 271.11(a) there are certain circumstances in which information will not be subject to discovery, admitted into evidence, or considered for other purposes in a Federal or State court proceeding for damages involving personal injury, wrongful death, or property damage. This information may not be used in such litigation when it is compiled or collected solely for the purpose of planning, implementing, or evaluating an RRP. Section 271.11(a) applies to information whether or not it is also in the Federal Government's possession.

FRA reformatted paragraph (a) for clarity from the NPRM. Paragraph (a) is divided into paragraphs (a)(1) and (2) after new introductory text. The formatting change does not, however, result in any substantive change to the paragraphs (a)(1) and (2). The new introductory text of paragraph (a) contains language implementing the section 20119(b) provision preventing the protections from becoming effective until one year after the adoption of the RRP rule.

Paragraph (a)(1) describes what may be considered ''information'' for the purposes of this section. Section 20119(a) identifies reports, surveys, schedules, lists, and data as the forms of information that FRA must consider in its study. However, FRA does not view the RSIA's list as limiting the forms of information that a rule may protect based on the study. In the statute, Congress directed FRA to consider the need for protecting information that includes a railroad's analysis of its safety risks and its statement of the mitigation measures to address those risks. *Id.* While the railroad is not required to provide in the RRP plan that it submits to FRA the results of the risk-based hazard analysis and the specific elimination or mitigation measures it will implement, the railroad may have a specific plan within its RRP that does contain this information. Therefore, to adequately protect this type of information, the term ''plan'' is included in the definition of ''information'' to cover a railroad's submitted RRP plan and any elimination or mitigation plans the railroad otherwise develops within its RRP. FRA also deems it necessary to include ''documents'' in this provision to maintain consistency and properly effectuate Congress' directive in section 20119.

This paragraph does not protect all information that is part of an RRP; these protections will extend only to information that is compiled or collected after February 17, 2021 solely for purpose of planning, implementing, or evaluating a risk reduction program. The term ''compiled or collected'' comes directly from section 20119(a). The term ''compiled'' refers to information that was generated by the railroad for the purposes of an RRP; whereas the term ''collected'' refers to information that was not necessarily generated for the purposes of the RRP, but was assembled in a collection for use by the RRP. It is important to note for collections, only the collection assembled for RRP purposes is protected; however, each separate piece of information that was not originally generated for use by the RRP remains subject to discovery and admission into evidence subject to any other applicable provision of law or regulation. For example, if a railroad originally collected or generated information for a non-RRP use, the rule does not protect that original non-RRP information, even if the railroad afterwards collects the information for protected RRP purposes. The rule would protect, however, the assembled collection of that information for RRP purposes.

In response to the SSP NPRM, APTA commented the rule text does not adequately explain the use of the term ''solely'' in the text of the regulation. *See* 81 FR 53879 (Aug. 12, 2016). APTA proposed that FRA either use a more appropriate term such as ''primarily'' or ''initially'' or that FRA define ''solely'' in the rule text, not just in the preamble. *Id.* FRA agrees. The use of the term ''solely'' is deliberate, and it is important that the term is understood as used within the four corners of the regulation. Therefore, FRA has included paragraph (a)(2), which defines the term ''solely,'' in both this rule and the § 270.105 of SSP final rule. *See* 81 FR 53900 (Aug. 12, 2016).

The term ''solely'' is intended to narrow circumstances in which the information will be protected. The use of the term ''solely'' means that the original purpose of compiling or collecting the information was

exclusively for the railroad's RRP. A railroad cannot compile or collect information for one purpose and then try to use paragraph (a) to protect that information because it uses that information for its RRP as well. The railroad's original and singular purpose for compiling or collecting the information must be for planning, implementing, or evaluating its RRP in order for the protections to be extended to that information. The term ''solely'' also means that a railroad must continue to use the information only for its RRP. If a railroad subsequently uses, for any other purpose, information the railroad initially compiled or collected for its RRP, paragraph (a) does not protect that information to the extent the railroad uses it for the non-RRP purpose. The use of that information within the railroad's RRP, however, will remain protected. If another provision of law or regulation requires the railroad to collect the information, the protections of paragraph (a) do not extend to that information because the railroad is not compiling or collecting the information solely for the purpose of planning, implementing, or evaluating an RRP. For example, 49 CFR 234.313 requires railroads to retain records regarding emergency notification system (ENS) reports of unsafe conditions at highway-rail grade crossings. Those individual records are not protected by § 271.11. However, if as part of its risk-based hazard analysis a railroad collects several of its § 234.313 reports from a specific time period for the sole purpose of determining if there are any hazards at highway-rail grade crossings, this collection will be protected as used in the RRP. If the railroad decides to use the collection for another purpose other than in its RRP, such as submitting it to an ENS maintenance contractor for routine maintenance, the protections do not extend to that non-RRP use.

APTA commented that the term ''sole purpose,'' because it is ill-defined and railroads use safety data to make many decisions, would effectively nullify this section's protections. APTA specifically recommended that FRA remove the phrase ''sole purpose,'' arguing that ''if a railroad is creating and using data for safety, it should be protected.'' APTA claims that it will ''not be difficult for plaintiffs' counsel to find any other use safety data has been used for,'' as railroads use safety data to make procurement, personnel, and other decisions on a routine basis. FRA is declining to implement this suggestion for several reasons. First, as discussed above, FRA has concluded this section should not protect information a railroad takes from its RRP to use for other purposes, and APTA's suggestion would allow a railroad to obtain protection for all safety information simply by incorporating it into a railroad's RRP. Second, FRA's changes to the information protections in § 271.11(a)(2) clarify that even if a railroad uses RRP information for other purposes, such as procurement or personnel decisions, the use of that information within the railroad's RRP remains protected. Finally, APTA's suggestion would create a discrepancy between the RRP and SSP final rules, and FRA's intent has always been to ensure the information protection provisions of both rules are consistent.

A railroad must compile or collect the information solely for the purpose of planning, implementing, or evaluating an RRP. The three terms—planning, implementing, or evaluating—come directly from section 20119(a). These terms cover the necessary uses of the information compiled or collected solely for the RRP. To properly plan and develop an RRP, a railroad will need to determine the proper processes and procedures to identify hazards, the resulting risks, and elimination or mitigation measures to address those hazards and risks. This planning will involve gathering information about the various analysis tools and processes best suited for that particular railroad's operations. This type of information is essential to the risk-based hazard analysis and is information that a railroad does not necessarily already have. In order for the railroad to plan its RRP, the protections are extended to the RRP planning stage. The NPRM used the term ''developing'' instead of ''planning''; however, to remain consistent with section 20119(a), FRA has determined that the term ''planning'' is more appropriate.

Based on the information generated by the risk-based hazard analysis, the railroad will implement measures to eliminate or mitigate the hazards and risks identified. To properly implement these measures, the railroad will need the information regarding the hazards and risks on the railroad's system identified during the development stage. Therefore, the protection of this information extends to the implementation stage.

The protections do not apply to information regarding mitigations that the railroad implements. Rather, § 271.11 protects the railroad's statement of mitigation measures, which could include various proposed and alternate mitigations for a specific hazard, that address the hazards identified by the risk-based hazard analysis. Additionally, § 271.11 protects the underlying risk analysis information that the implemented mitigation measure addresses. For example, if a railroad builds a structure to address a risk identified by the risk-based hazard analysis, this section does not protect the information regarding that structure (*e.g.,* blueprints, contracts, permits, etc.). This section does protect, however, the underlying risk-based hazard analysis that identified the hazard and any statement of mitigations that included the structure.

The protections also do not apply to any hazards, risks, or mitigations that fall under the exclusive jurisdiction of another Federal agency. If FRA does not have jurisdiction over a hazard, risk, or mitigation, then the protections under this paragraph cannot cover that hazard, risk, or mitigation.

The railroad must also evaluate whether the measures it implements to mitigate or eliminate the hazards and risks identified by the risk-based hazard analysis are effective. To do so, it will need to review the information developed by the risk-based hazard analysis and the methods used to implement the elimination/mitigation measures. This section protects the use of this information in the evaluation of the railroad's RRP.

The information covered by this section shall not be subject to discovery, admitted into evidence, or considered for other purposes in a Federal or State court proceeding that involves a claim for damages involving personal injury, wrongful death, or property damage. The first two situations come from section 20119(a); however, FRA determined that for the protections to be effective they must also apply to any other situation where a litigant might try to use the information in a Federal or State court proceeding that involves a claim for damages involving personal injury, wrongful death, or property damage. For example, this section prohibits a litigant from admitting into evidence a railroad's risk-based hazard analysis. Nonetheless, without the additional language: ''or considered for other purposes,'' a litigant could use the railroad's risk-based hazard analysis for the purpose of refreshing the recollection of a witness or an expert witness could use the analysis to support an opinion. The additional language ensures that the protected information remains out of such a proceeding completely. The protections would be ineffective if a litigant were able to use the information in the proceeding for another purpose. To encourage railroads to perform the necessary vigorous risk analysis and to

implement truly effective elimination or mitigation measures, the protections must extend to any use in a proceeding.

This section applies to Federal or State court proceedings that involve a claim for damages involving personal injury, wrongful death, or property damage. This means, for example, if a proceeding has a claim for personal injury and a claim for property damage, the protections extend to that entire proceeding; therefore, a litigant cannot use any of the information protected by this section as it applies to either the personal injury or property damage claim. Section 20119(a) required the study to consider proceedings that involve a claim for damages involving personal injury or wrongful death; however, to effectuate Congress' intent behind section 20156, that railroads engage in a systematic and candid hazard analysis and develop meaningful mitigation measures, FRA has determined that it is necessary for the protections to extend to proceedings that involve a claim solely for property damage. The typical railroad accident resulting in injury or death also involves some form of property damage. Without extending the protection to proceedings that involve a claim for property damage, a litigant could bring two separate claims arising from the same incident in two separate proceedings, the first for property damages and the second one for personal injury or wrongful death, and be able to conduct discovery regarding the railroad's risk analysis and to introduce this analysis in the property damage proceeding but not in the personal injury or wrongful death proceeding. This would mean that a railroad's risk analysis could be used against the railroad in a proceeding for damages. If this were the case, a railroad would be hesitant to engage in a systematic and candid hazard analysis and develop meaningful elimination or mitigation measures. Such an approach would be nonsensical and would completely frustrate Congress' intent in providing FRA the ability to protect that information which is necessary to ensure that railroads perform open and complete risk assessments and select and implement appropriate mitigation measures. Therefore, to be consistent with Congressional intent behind section 20156, FRA is extending the protections in paragraph (a) to proceedings that involve a claim for property damage. Further, RSAC recommended in the context of the SSP rulemaking that FRA extend the protections in this way to proceedings that involve a claim for property damage. *See* 81 FR 53881 (Aug. 12, 2016).

Paragraph (b) ensures the protections in paragraph (a) do not extend to information compiled or collected for a purpose other than specifically identified in paragraph (a). This type of information shall continue to be discoverable, admissible into evidence, or considered for other purposes if it was before the date the protections take effect. The types of information that will not receive the protections paragraph (a) provides include: (1) Information compiled or collected on or before February 17, 2021; (2) information compiled or collected on or before February 17, 2021 and continues to be compiled or collected, even if used to plan, implement, or evaluate a railroad's SSP; or (3) information compiled or collected after February 17, 2021 for a purpose other than specifically identified in paragraph (a) of this section. Paragraph (b) affirms FRA's meaning for the term ''solely'' in paragraph (a)—that a railroad may not compile or collect information for a different purpose and then expect to use paragraph (a) to protect that information just because the information is also used in its RRP. In such cases the information is unprotected and will continue to be unprotected.

Examples of the types of information that paragraph (b) applies to may be records related to prior accidents/incidents and reports prepared in the normal course of railroad business (such as inspection reports). Generally, this type of information is often discoverable, may be admissible in Federal and State proceedings, and should remain discoverable and admissible where it is relevant and not unduly prejudicial to a party after the implementation of this part. However, FRA recognizes that evidentiary decisions are based on the facts of each particular case; therefore, FRA does not intend this to be a definitive and authoritative list. Rather, FRA merely provides these as examples of the types of information that paragraph (a) is not intended to protect after the implementation of this part.

Under paragraph (b)(2), if a railroad compiled or collected certain information that was subject to discovery, admissibility, or consideration for other purposes before the protections take effect and the railroad continues to collect the same type of information pursuant to its RRP required by this part, that information will not be protected by paragraph (a) of this section. For example, before this section takes effect and all else being equal, a litigant that would have been able to have admitted into evidence certain information the railroad compiled will still be able to have that type of information admitted after this section takes effect even if the railroad compiles the information pursuant to this rule. The protections are designed to apply only when the original purpose for the generation of the information was for an RRP required by this part. The original purpose of the generation of the information for the RRP-like programs that existed before the RRP rule would be for an RRP required by this part; therefore, such information is not protected by paragraph (a).

While objecting to any information protections whatsoever, AAJ also commented that any protections FRA does promulgate ''should be clear and not result in satellite litigation.'' AAJ is particularly concerned that the information protections would increase litigation and litigation costs by generating litigation over which information the rule protects or does not protect. AAJ therefore recommends that FRA should ''require all applicable railroads [to] report all classes of documents that would remain discoverable.'' ARLA, Labor Organizations I, and Labor Organizations II similarly urged FRA to reduce litigation costs by including a list of documents currently available for use in litigation in the final rule. Labor Organizations I and Labor Organizations II also asked FRA to include a list of examples of information currently discoverable and admissible. AAJ, ARLA, Labor Organizations I, and Labor Organizations II all provided FRA examples of such a list either in comments or during the RRP Working Group process.

As discussed, FRA changed the proposed information protection to include a definition of ''solely'' that further clarifies what information § 271.11 protects and does not protect. FRA does not, however, believe that AAJ's proposal to require all railroads to report documents that remain discoverable or include lists of discoverable information as other commenters suggested would be effective. First, the suggested approach does not account for future information railroads will compile or collect the information for non-RRP purposes, which § 271.11 will not protect. Railroads also cannot predict what future statutes or regulations will require them to collect information. Such reports or lists, therefore, would fail to include vast swathes of future information that should be discoverable. Further, courts are responsible for determining which documents are

discoverable under the applicable rules of discovery and evidence, not railroads. In addition, the commenters have not suggested how FRA would ensure a railroad accurately reported which documents would remain discoverable or how FRA would update lists. FRA therefore declines to require railroads to report documents that will remain discoverable and declines to publish lists of discoverable documents.

This section is not intended to replace any other protections provided by law or regulation. Accordingly, paragraph (c) states the protections in this section will not affect or abridge in any way any other protection of information provided by another provision of law or regulation. Any such provision of law or regulation shall apply independently of the protections provided by this section. While the NPRM did not propose this provision, FRA believes this language should be non-controversial. The SSP final rule also contains the same language. *See* 81 FR 53882 (Aug. 12, 2016).

Paragraph (d) clarifies that a litigant cannot rely on State discovery rules, evidentiary rules, or sunshine laws to require the disclosure of information protected by paragraph (a) in a Federal or State court proceeding for damages involving personal injury, wrongful death, or property damage. This is the same language that proposed paragraph (c) in the NPRM contained. Because FRA did not receive any comments on this proposal, FRA refers readers to the NPRM's discussion. *See* 80 FR 10966 (Feb. 27, 2015).

Paragraph (e) contains new language clarifying that § 271.11 does not protect information during civil or criminal law enforcement proceedings. For example, § 271.11 would not apply to a civil or criminal action brought to enforce Federal railroad safety laws, or proceedings such as a civil action brought by the Department of Justice under the Clean Water Act to address a discharge of pollutants into waters of the United States following a rail accident. Because paragraph (a) of this section plainly states that the information protections apply to ''Federal or State court proceeding for damages involving personal injury, wrongful death, or property damage,'' FRA believes a court would not find that the protections apply to a civil or criminal enforcement case. Nevertheless, to help ensure no attempt is made to rely on the rule's information protections in a civil or criminal enforcement proceeding, paragraph (e) explicitly states that § 271.11 does not apply to civil or criminal enforcement actions. FRA plans to similarly clarify the information protection provision in § 270.105 of the SSP rule, which also apply only to Federal or State court proceedings for damages involving personal injury, wrongful death, or property damage.

The NPRM proposed that FRA might extend the information protections in an SSP final rule to the RRP final rule. The effect of this approval would have been that the protections for the RRP final rule would be applicable one year after publication of the SSP final rule. FRA sought comment on this proposal, and AAR/ASLRRA commented in support. AAJ, however, objected to FRA's proposal to use the information protection provisions in the SSP final rule to protect RRP information. AAJ stated FRA's proposal would ''prematurely curtail the rights of rail accident victims'' and ''cut short the full regulatory process on the Risk Reduction Rule.'' Instead, AAJ suggests FRA should stay the effective date for the SSP final rule until the RRP final rule goes into effect.

Upon further consideration, FRA determined this final rule should implement the information protections for RRPs, not the SSP final rule. Section 20119(b) (emphasis added) states ''*Any* such rule prescribed pursuant to this subsection shall not become effective until 1 year after its adoption.'' Thus, FRA concluded the RSIA requires each rule implementing information protections to have its own independent implementation timeline. FRA believes this approach is a better and more reasonable interpretation of Congressional intent in section 20119(b). Further, the modified approach ensures FRA has complied with notice and comment procedures of the Administrative Procedure Act for both the RRP and SSP rulemakings.

Section 271.13—Determination of Inadequate Safety Performance

This section describes how FRA will determine which railroads must comply with this rule because they have inadequate safety performance. This section explains that FRA's analysis has two phases: A statistically-based quantitative analysis phase and then a qualitative assessment phase. Only railroads identified as possibly having inadequate safety performance in the quantitative analysis will continue to the qualitative assessment, as discussed further below.

The RSIA directs FRA to require railroads with inadequate safety performance (as determined by FRA) to develop and implement an RRP. *See* 49 U.S.C. 20156(a)(1). Before publishing the NPRM, FRA discussed potential definitions of inadequate safety performance during RSAC Working Group meetings and conference calls. Based on these discussions, which explored various ASLRRA concerns, FRA developed a methodology to determine inadequate safety performance. FRA received tentative agreement from the RRP Working Group on this methodology, but did not seek consensus.

The RRP NPRM proposed a two-phase annual process FRA would use to determine if a railroad's safety performance was inadequate. The proposed process would evaluate only railroads not already complying with an SSP or RRP rule, including voluntarily-compliant railroads.

For the first phase of the process, FRA proposed conducting a statistical quantitative analysis to determine a railroad's safety performance index. This quantitative analysis would use railroad data maintained by FRA from the three full calendar years before the analysis. As proposed, the quantitative analysis would utilize the following four factors: (1) On-duty employee fatalities; (2) FRA reportable on duty employee injury/illness rate; (3) FRA reportable accident/incident rate; and (4) FRA violation rate. The proposed quantitative analysis would specifically identify railroads that either had a fatality or were at or above the 95th percentile in at least two of the three other factors.

For the second phase of the process, FRA proposed performing a qualitative assessment of railroads that the quantitative analysis identified as warranting further review. FRA proposed notifying a railroad identified for the qualitative assessment and providing it an opportunity to comment and submit documentation supporting any claim that it has adequate safety performance. FRA also proposed requiring an identified railroad to inform its employees of the FRA notification so that the employees could submit confidential comments on the matter directly to FRA. FRA's qualitative analysis would then consider comments from the railroad and the railroad's employees, as well as any other pertinent evidence, in determining the railroad's safety performance. Following the qualitative assessment, FRA would inform an identified railroad whether or not it must comply with the RRP rule.

As an initial matter, FRA notes the language in this section in the final rule uses the present tense, while the proposed rule used future tense. This change does not affect the substance of this section.

The National Safety Council (NSC) commented that programs like RRP are ''essential safety tools for all companies, irrespective of past safety performance.'' NSC claims that railroads that wait to implement an RRP until identified with inadequate safety performance are ''weak links in the system'' and that creating an inadequate safety performance threshold for smaller railroads will make RRP compliance punitive, rather than a ''safety best practice that benefits all railroads and is part of normal planning and operations.'' NSC suggests that all railroads should be encouraged to implement RRPs, and that FRA should determine which railroads' safety performance warrants additional regulatory oversight.

FRA agrees with NSC that encouraging all railroads to implement risk reduction programs is important. As mandated by section 20156(a)(4), and as proposed in the NPRM, this final rule allows railroads to voluntarily comply. This final rule's information protection provisions will also encourage voluntary RRP compliance by ensuring that information a railroad compiles or collects solely for RRP purposes is not discoverable or admissible in certain litigation proceedings. While this final rule encourages voluntary compliance, FRA must fulfill the clear RSIA mandate to require RRP compliance for railroads with inadequate safety performance, as determined by FRA. FRA therefore concludes that this final rule encourages voluntary compliance while also meeting the RSIA mandate to require compliance for railroads demonstrating inadequate safety performance.

In response to both the NPRM and DOT's regulatory review initiative, ASLRRA expressed concern that the methodology proposed in the NPRM for identifying railroads with inadequate safety performance would result in a disproportionate number of the smallest railroads being selected simply because they have a lower number of employees. To assess this concern, FRA conducted several analyses of data from FRA's Rail Accident/Incident Reporting System (RAIRS), the system that would provide the data for determining which railroads demonstrate inadequate safety performance. To approximate the NPRM's proposed methodology, FRA conducted the analyses for the 3-year period from 2016 through 2018, the latest years for which a full 12 months' data were available at the time of the analysis.

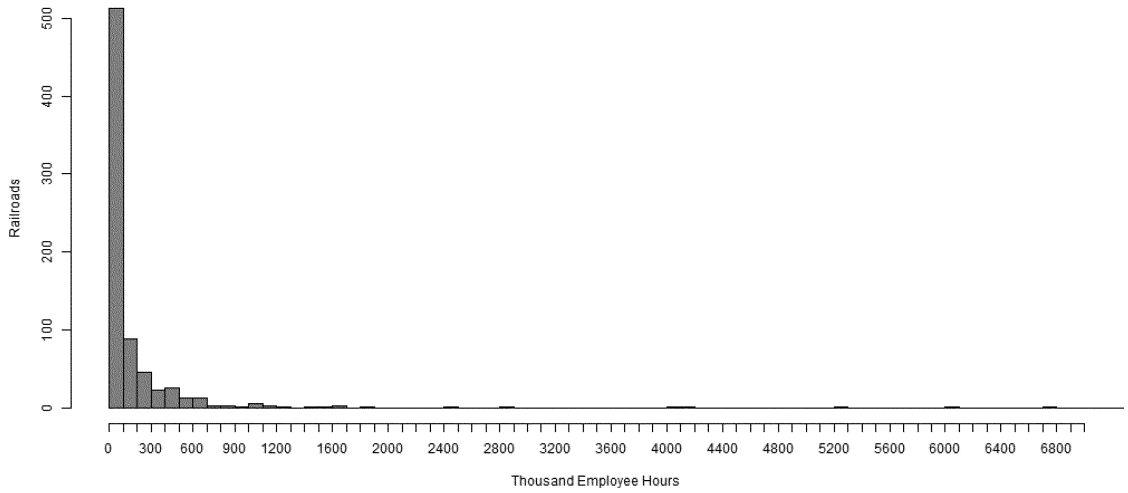
As part of the first analysis, FRA identified all Class II and Class III railroads the NPRM's methodology would analyze for inadequate safety performance (all Class II and III railroads that would be subject to the rule; a total of 745 railroads). For these railroads, FRA used data from 2016 through 2018 to calculate: (1) The average total train miles operated, and (2) average total employee hours. FRA then calculated the same averages for the 11 railroads within the group of 745 that reported an employee fatality and the other 734 railroads that did not report an employee fatality during that same time period. As Table 3 shows, between 2016 and 2018, the entire pool of 745 Class II and Class III railroads reported an average of 213,466 total train miles operated and 168,476 employee labor hours. The 11 railroads reporting an employee fatality had substantially higher averages, with 3,147,087 train miles operated and 2,081,274 employee hours, while the 734 railroads without an employee fatality reported an average of 169,501 total train miles operated, and 139,810 employee labor hours, which is substantially below the overall averages for the entire population of 745 railroads.

TABLE 3—OPERATIONAL DATA OF CLASS II AND CLASS III FREIGHT RAILROADS BETWEEN 2016 AND 2018

	Number of railroads	Average train miles	Average employee hours
Railroads on which employee fatalities occurred	11	3,147,087	2,081,274
Railroads without employee fatalities	734	169,501	139,810
All	745	213,466	168,476

Figure 1 contains a histogram showing the distribution of Class II and Class III railroads by reported employee labor hours between 2016 and 2018. Each tick mark along the x-axis represents a range of employee hours. The bar heights along the y-axis illustrate the number of railroads that reported employee labor hours within a given range of employee hours. Figure 1 demonstrates that the vast majority of Class II and III railroads report approximately 100,000 annual employee labor hours.

Figure 1. Distribution of Class II and Class III railroads by employee labor hours reported between 2016 and 2018.



Figures 2 and 3 show the distribution of Class II and Class III railroads by train miles reported between 2016 and 2018. (FRA has broken this data into 2 separate charts to ensure legibility). The number of train miles reported during this period ranged from zero to about 15 million. As with Figure 1, the bar heights along the y-axis in Figures 2 and 3 indicate how many railroads reported train miles in the ranges along the x-axis. Figures 2 and 3 demonstrate that the vast majority of Class II and Class III railroads reported 100,000 train miles or less between 2016 and 2018.

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Figure 2. Distribution of Class II and Class III railroads by train miles reported between 2016 and 2018, for railroads reporting fewer than 5 million train miles.

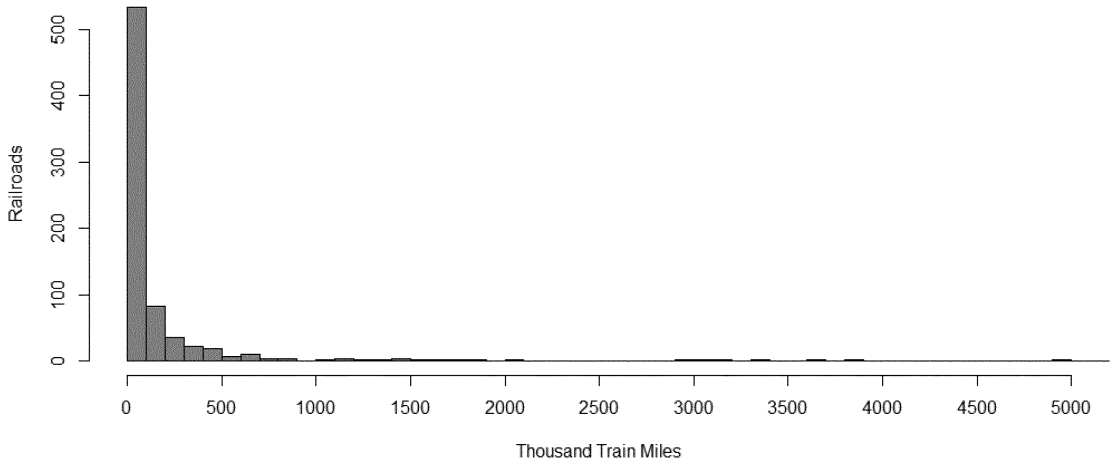
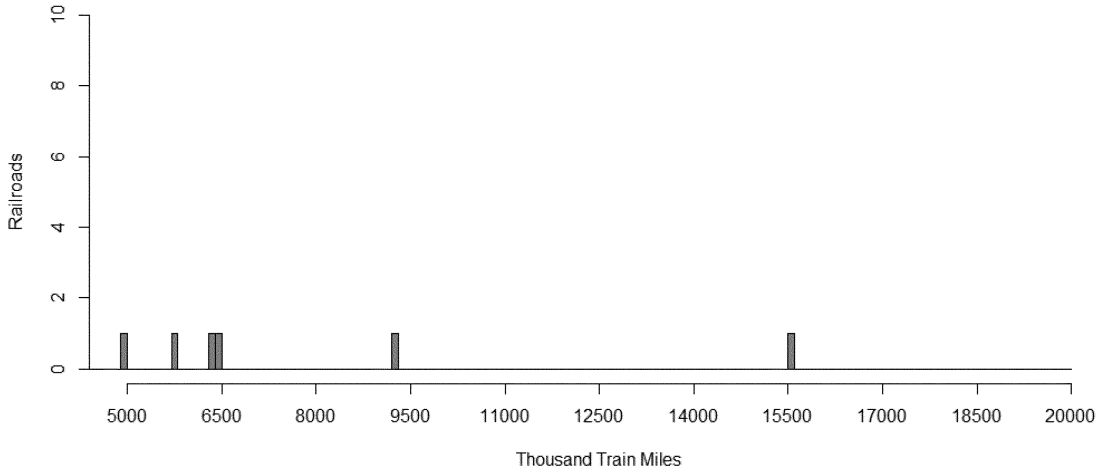


Figure 3. Distribution of Class II and Class III railroads by train miles reported between 2016 and 2018, for railroads reporting more than 5 million train miles.



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The data presented in Table 1, as well as the illustrations in Figures 1, 2, and 3, strongly suggest that the overall averages for Class II and Class III railroads are influenced by a small number of larger Class II or Class III railroads.

As a second analysis, FRA used the NPRM's quantitative analysis methodology to evaluate the 734 Class II and III railroads that did not report an employee fatality. FRA excluded the 11 railroads that reported an employee fatality from this analysis because the NPRM's quantitative analysis would automatically advance them to the qualitative assessment. *See* 80 FR 10967 (Feb 27, 2015). Using the NPRM's quantitative analysis methodology, FRA identified railroads for further analysis (*i.e.,* identified railroads for qualitative assessment) and found that these railroads reported an average 24,645

total train miles and 43,040 employee hours between 2016 and 2018. *See* Table 4. These averages are substantially lower than averages for both the entire pool of Class II and Class III railroads (*see* Table 3) and the pool of railroads not reporting an employee fatality. FRA believes that the population of railroads selected for further analysis should, with respect to size, resemble the overall population from which they were drawn. The fact that the railroads selected by the NPRM's methodology are so different from the overall population of Class II and Class III railroads indicates that the NPRM's quantitative analysis potentially over-identified smaller railroads for the qualitative assessment.

Despite the numbers above, FRA considered the possibility that the NPRM's quantitative analysis fairly identified smaller Class II and Class III railroads as possibly demonstrating inadequate safety performance. Accordingly, FRA conducted a third analysis to test this possibility. In this analysis, FRA compared the number of railroads selected under the NPRM's proposed quantitative analyses methodology with the number of railroads reporting accidents but no fatalities (the majority of railroads selected using the NPRM methodology were included in part because of their accident rates). As Table 4 shows, the population of all railroads on which a nonfatal train equipment accident/incident occurred reported an average of 390,091 total train miles and an average of 348,824 employee labor hours between 2016 and 2018. This suggests that the railroads with inadequate safety performance should not only be the smaller railroads. For example, assuming a full-time employee works 2080 hours per year, the railroads selected for qualitative assessment using the NPRM's methodology averaged 7 employees each, while the railroads experiencing a nonfatal train equipment accident/incident between 2016 and 2018 had an estimated 56 employees on average. Based on this result, FRA shares ASLRRA's concern that the proposed methodology would over-select the smallest railroads.

TABLE 4—COMPARISON OF DATA FOR RAILROADS IDENTIFIED BY THE NPRM'S QUANTITATIVE ANALYSIS (EXCLUDING THOSE WITH AT LEAST ONE FATAL ACCIDENT BETWEEN 2016–2018) AND DATA FOR ALL CLASS II AND CLASS III FREIGHT RAILROADS ON WHICH NONFATAL TRAIN ACCIDENTS/INCIDENTS OCCURRED

Class II and Class III railroads, 2016–2018	Number of railroads	Average train miles	Average employee hours
Railroads selected under the NPRM-proposed method	12	24,645	43,040
Railroads with nonfatal train accidents/incidents	204	390,091	348,824

Therefore, as explained below, FRA has changed the quantitative analysis methodology to avoid over-selecting the smallest railroads for the qualitative assessment. Applying the changed methodology to RAIRS data, railroads identified for quantitative assessment on average reported 106,520 train miles operated and 258,881 employee hours from 2016 through 2018. These averages are much closer to the averages for the entire pool of Class II and III freight railroads that the quantitative analysis will initially evaluate. As Figures 4 and 5 show, 10 out of 12 railroads identified for qualitative assessment using the NPRM's quantitative analysis reported under 50,000 total train miles, but only 4 out of 15 railroads identified using the final rule's quantitative analysis methodology reported under 50,000 total train miles operated.

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Figure 4. Number of railroads without fatalities identified for further analysis by the NPRM's quantitative analysis by total train miles (2016-2018).

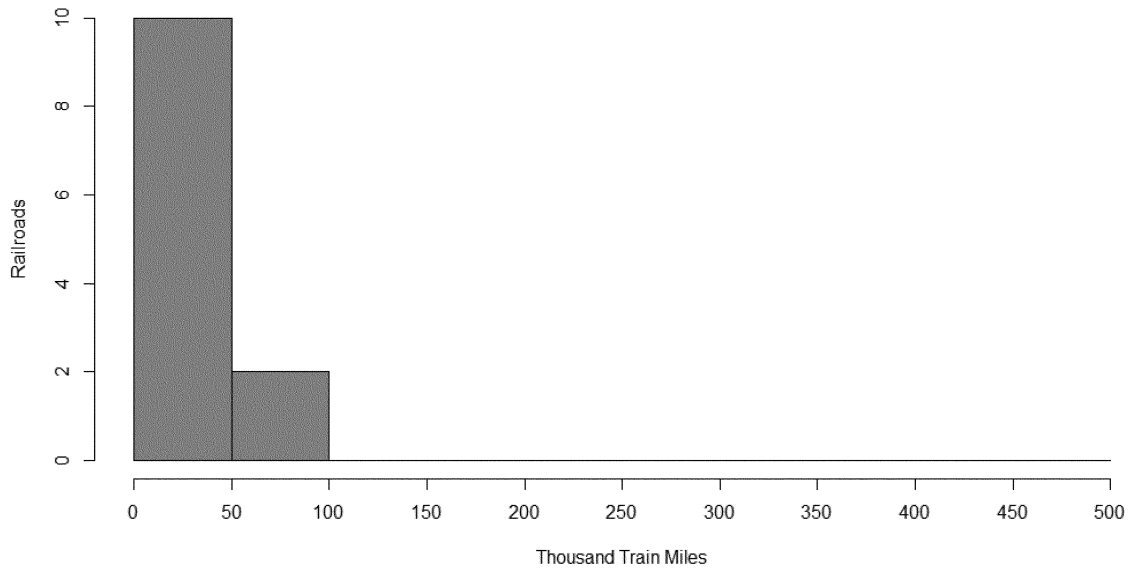
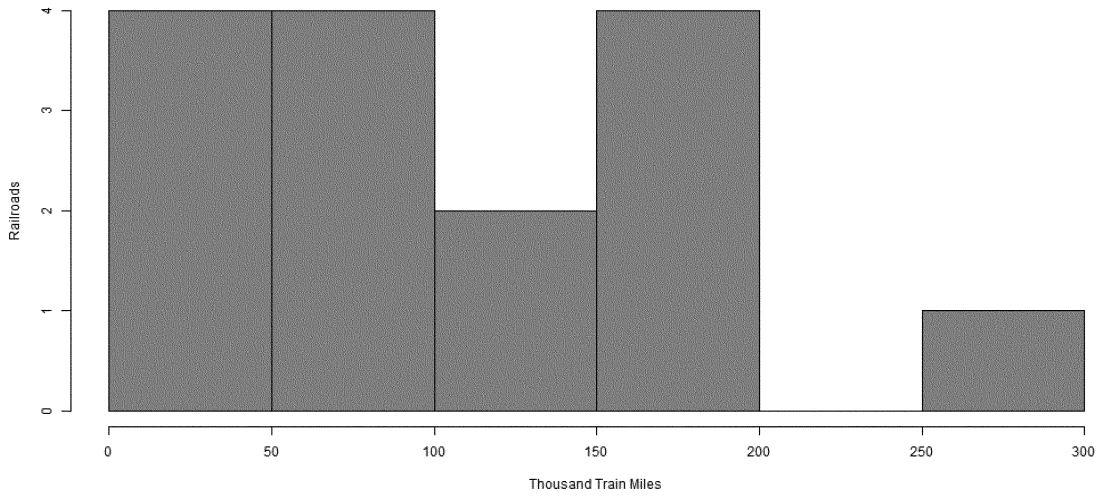


Figure 5. Number of railroads without fatalities identified for further analysis by the final rule's quantitative analysis by total train miles (2016-2018).



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These numbers suggest that the changed quantitative analysis method is less likely to identify railroads for qualitative analysis that are statistical outliers or aberrations due solely to their small size. FRA discusses the specific changes it has made to the rule text to reflect the new methodology (and other changes) in the section-by-section analysis below. For clarity, FRA is discussing each provision of this important section, even where FRA did not change certain provisions from the NPRM.

Paragraph (a) describes FRA's methodology as a two-phase annual analysis, comprised of both a quantitative analysis and a qualitative assessment. This analysis will not include railroads excluded under § 271.3(b) (*e.g.,* commuter or intercity passenger railroads that are subject to FRA SSP requirements), railroads otherwise required to comply with this rule (*i.e.,* Class I railroads and railroads previously determined to have inadequate safety performance under this section), railroads that voluntarily comply with this rule under proposed

§ 271.15, and new railroads that have reported accident/incident data to FRA for fewer than three years. However, paragraph (a)(2) states FRA will include new railroads formed through an amalgamation of operations (for example, railroads formed through consolidations, mergers, or acquisitions of control) in the analysis using the combined accident/incident data of the pre-amalgamation entities.

Paragraph (b) describes the quantitative analysis, which makes a threshold identification of railroads that might have inadequate safety performance. This paragraph includes a preliminary selection FRA has added to the quantitative analysis to both address ASLRRA's concern that the NPRM's proposed methodology would over-select the smallest railroads and to filter out railroads with small enough operations that the rate-based analysis would lack statistical stability. This preliminary selection will help avoid over-selecting the smallest railroads by utilizing the absolute number (rather than rates) of two factors regarding a railroad's safety performance; FRA selected the specific factors in response to comments from the ASLRRA during RSAC discussions. Addition of the preliminary selection resulted in FRA reorganizing several paragraph (b) NPRM provisions. Paragraph (b)(1) specifies the quantitative analysis will be statistically-based and include each railroad within the scope of the analysis using historical safety data FRA maintains for the three most recent full calendar years. The quantitative analysis will include both the added preliminary selection and a rate-based analysis, and only railroads the preliminary selection identifies will proceed to the rate-based analysis.

Paragraph (b)(1)(i) describes the preliminary selection FRA has added to the quantitative analysis. The first factor for the preliminary selection, in paragraph (b)(1)(i)(A), is a railroad's number of worker on duty fatalities during the 3-year period, determined using Worker on Duty—Railroad Employee (Class A), Worker on Duty—Contractor (Class F), and Worker on Duty—Volunteer (Class H) information reported on FRA Form 6180.55 under FRA's accident/incident reporting regulations in part 225.

The second factor for the preliminary selection, in paragraph (b)(1)(i)(B), is a railroad's number of FRA reportable worker on duty injuries/illnesses during the 3-year period, calculated using ''Worker on Duty—Railroad Employee'', Worker on Duty—Contractor (Class F), and Worker on Duty—Volunteer (Class H) information reported on FRA Form 6180.55 under FRA's accident/incident reporting regulations in part 225, added to a railroad's number of FRA reportable rail equipment accidents/incidents during the 3-year period, using information reported on FRA Form 6180.54.

For railroads with operations large enough for rates to be statistically stable, FRA believes that using rates enables a fair comparison between operations that might otherwise be very different in size. As paragraph (b)(1) explains, FRA will perform the next rate-based analysis only on railroads the preliminary selection identifies. The rate-based analysis will incorporate three factors regarding a railroad's safety performance. The first factor, described in paragraph (b)(1)(ii)(A) (proposed paragraph (b)(1)(i) in the NPRM), is a railroad's number of on-duty employee fatalities during the 3-year period, using Worker on Duty—Railroad Employee (Class A) Worker on Duty—Contractor (Class F), and Worker on Duty—Volunteer (Class H) information reported on FRA Form 6180.55 under FRA's accident/incident reporting regulations in part 225.

The second factor, described in paragraph (b)(1)(ii)(B) (proposed paragraph (b)(1)(ii) in the NPRM), is a railroad's FRA Worker on Duty injury/illness rate, calculated using Worker on Duty—Railroad Employee (Class A) Worker on Duty—Contractor (Class F), and Worker on Duty—Volunteer (Class H) information reported on Form 6180.55 under FRA's accident/incident reporting regulations in part 225. FRA will calculate this rate using the following formula:

Injury/Illness Rate = (Total FRA Reportable Worker on Duty Injuries + Total FRA Reportable Worker on Duty Illnesses over a 3-year Period) ÷ (Total Employee Hours over a 3-year Period/200,000)

This calculation gives the rate of employee injuries and illnesses per 200,000 employee hours calculated over a 3-year period.

In the NPRM, the calculation for this factor specified ''Total FRA Reportable On Duty Employee *Occupational* Illnesses over a 3-year period'' (emphasis added). FRA is removing the term ''occupational'' from the calculation in the final rule because part 225 does not always use the term ''occupational illness.'' For example, Form 6180.55 is titled ''Railroad Injury and Illness Summary.'' For clarity, FRA is phrasing the requirement in terms of illnesses a railroad must report using Form 6180.55. This change does not affect the substance of this provision.

Additionally, while the NPRM proposed also using information reported on Form 6180.55a (which a railroad must file for each reportable injury or illness) for both the first and second factors of the quantitative analysis, FRA decided the summary information reported on Form 6180.55 is sufficient for these calculations. This change also does not affect the substance of this provision.

AAR/ASLRRA (jointly) and ASLRRA (independently) commented that fatalities and injuries should only count if they relate to the operation of a railroad (*i.e.,* not natural causes, suicides, etc.). AAR/ASLRRA also commented that few Class III railroads approach the 200,000-person-hour denominator in the employee injuries and occupational illnesses calculation, which can skew results. While FRA generally agrees fatalities that do not relate to railroad operations are not necessarily indicative of inadequate safety performance, the quantitative analysis in paragraph (b) is merely a threshold determination and cannot account for every mitigating circumstance. As such, the qualitative assessment paragraph (c) establishes (discussed below) gives a railroad (and railroad employees) the opportunity to provide any such mitigating information regarding the railroad's number of fatalities, and FRA will consider that information when making its final determination. Regarding AAR/ASLRRA's concern that the 200,000-person-hour denominator would skew results for small railroads, although FRA does not agree that a scaling factor alone induces sampling bias, FRA does agree that the results of the quantitative analysis presented in the NPRM did over-select the smallest railroads. FRA therefore added the preliminary selection to the quantitative analysis to avoid over-selecting the smallest railroads, as discussed above.

The third factor, described in paragraph (b)(1)(ii)(C) (proposed paragraph (b)(1)(iii) in the NPRM), is a railroad's FRA reportable rail equipment accident/incident rate, calculated using information reported on FRA Form 6180.54 and Form 6180.55. FRA will calculate this rate using the following formula:

Rail Equipment Accident/Incident Rate = Total FRA Reportable Rail Equipment Accidents/Incidents over a 3-year Period ÷ (Total Train Miles over a 3-year Period/1,000,000)

This calculation gives the rate of rail equipment accidents/incidents per

1,000,000 train miles calculated over a 3-year period.

Paragraph (b)(1)(iv) of the NPRM proposed a fourth factor for the rate-based analysis: A railroad's FRA violation rate, calculated using FRA's field inspector data system. AAR/ASLRRA and ASLRRA commented that the proposed violation rate factor was meaningless because many violations relate to records or are dropped by FRA due to mitigating circumstances or failure to adequately document the violation. In response to DOT's regulatory review initiative, ASLRRA also commented that including violations, which are at an inspector's discretion, could be utilized to ensure a short line's inclusion. FRA's analysis suggests that a very small number of railroads were selected for qualitative assessment because of violation rates, and that removing this factor would likely not materially affect the number of railroads that are determined to have inadequate safety performance. Given the commenters' concerns and the negligible effect of removing this factor, in this final rule, FRA is not including a railroad's FRA violation rate as a factor in the rate-based analysis. To the extent a railroad's FRA violations may indicate inadequate safety performance, FRA will consider them as ''other pertinent information'' during the qualitative assessment, as discussed below in the section-by-section analysis for paragraph (c)(2) of this section.

Paragraph (b)(2)(i) states the preliminary selection will identify a railroad for rate-based analysis if the railroad meets at least one of two conditions. The first condition is when a railroad has one or more fatalities. FRA considers an on duty employee fatality a strong indication of inadequate safety performance. If a railroad has at least one fatality within the 3-year period of the quantitative analysis, FRA will examine that railroad further in the rate-based analysis.

The second condition is when a railroad was at or above the 90th percentile in the factor described in paragraph (b)(1)(i)(B) of this section (*e.g.,* the sum of a railroad's FRA injury/illness count and its FRA accident/incident count). For example, if the scope of data includes a set of 100 railroads, FRA would identify the railroads with the ten highest total injury/illness and accident/incident count.

For railroads that advance to the rate-based analysis from the preliminary selection, the rate-based analysis will identify railroads as possibly having inadequate safety performance based on the factors described in paragraph (b)(2)(ii). Paragraph (b)(2)(ii) (proposed paragraph (b)(2) in the NPRM) states the rate-based analysis will identify a railroad as possibly having inadequate safety performance if at least one of two conditions is met. The first condition, described in paragraph (b)(2)(ii)(A), is when a railroad has one or more fatalities. As stated above regarding the preliminary selection, FRA considers an on-duty employee fatality a strong indication of inadequate safety performance. If a railroad has at least one fatality within the 3-year period of the quantitative analysis, FRA will examine that railroad further in the qualitative assessment.

AAR/ASLRRA commented paragraph (b)(2)(i) in the NPRM stated the quantitative analysis would identify a railroad if the ''railroad has one or more fatalities,'' without reference to the 3-year period. Corresponding paragraph (b)(2)(ii)(A) in the final rule clarifies that the rate-based analysis will identify a railroad if it has one or more fatalities ''as calculated in paragraph (b)(1)(ii)(A).'' Because paragraph (b)(1)(ii)(A) specifically references the 3-year period, the final rule clarifies the 3-year period applies when identifying railroads with one or more fatalities.

The second condition, described in paragraph (b)(2)(ii)(B), is when a railroad is at or above the 90th percentile in either of the factors described in paragraphs (b)(1)(ii)(B) and (C) of this section (*e.g.,* a railroad's injury/illness rate, or FRA accident/incident rate). FRA will examine further those railroads identified in one or more of these factors in the qualitative assessment. Paragraph (b)(2)(ii) in the NPRM proposed that the quantitative analysis would identify for further analysis railroads at the 95th percentile in at least two of three factors. (The third factor was a railroad's FRA violation rate, which FRA has removed from the rate-based analysis as discussed above.) The NPRM explained that this percentile would identify approximately 42 railroads over a five-year period, and that FRA considered this a reasonable pool of railroads to examine further in the qualitative assessment. *See* 80 FR 10967 (Feb. 2015). While FRA still believes this is a reasonable number of railroads to examine in the qualitative analysis, the addition of the preliminary selection to the ISP determination process will reduce the number of railroads considered in the rated-based analysis. The removal of a railroad's FRA violation rate from consideration will also reduce the number of factors considered when identifying railroads for the qualitative assessment. To obtain a similar pool of railroads for the qualitative analysis under the final rule, FRA has therefore changed the second condition of the rate-based analysis to the 90th percentile of railroads in either of the two remaining factors. Preliminary analyses estimate FRA's approach will identify approximately 40–45 railroads over a five-year period,[18] which is consistent with FRA's position in the NPRM that 43 potential railroads are a reasonable pool to examine further in the qualitative analysis.

AAR/ASLRRA commented that when FRA determines whether it should subject a railroad to a qualitative analysis, the two conditions should be causally-related, and not two completely unrelated measurements. Specifically, AAR/ASLRRA commented that the conditions related to employee casualties and reportable accident/incident data should be related to railroad operations. Issues regarding causation, however, will be part of the qualitative analysis. FRA has therefore not made any changes in response to this comment.

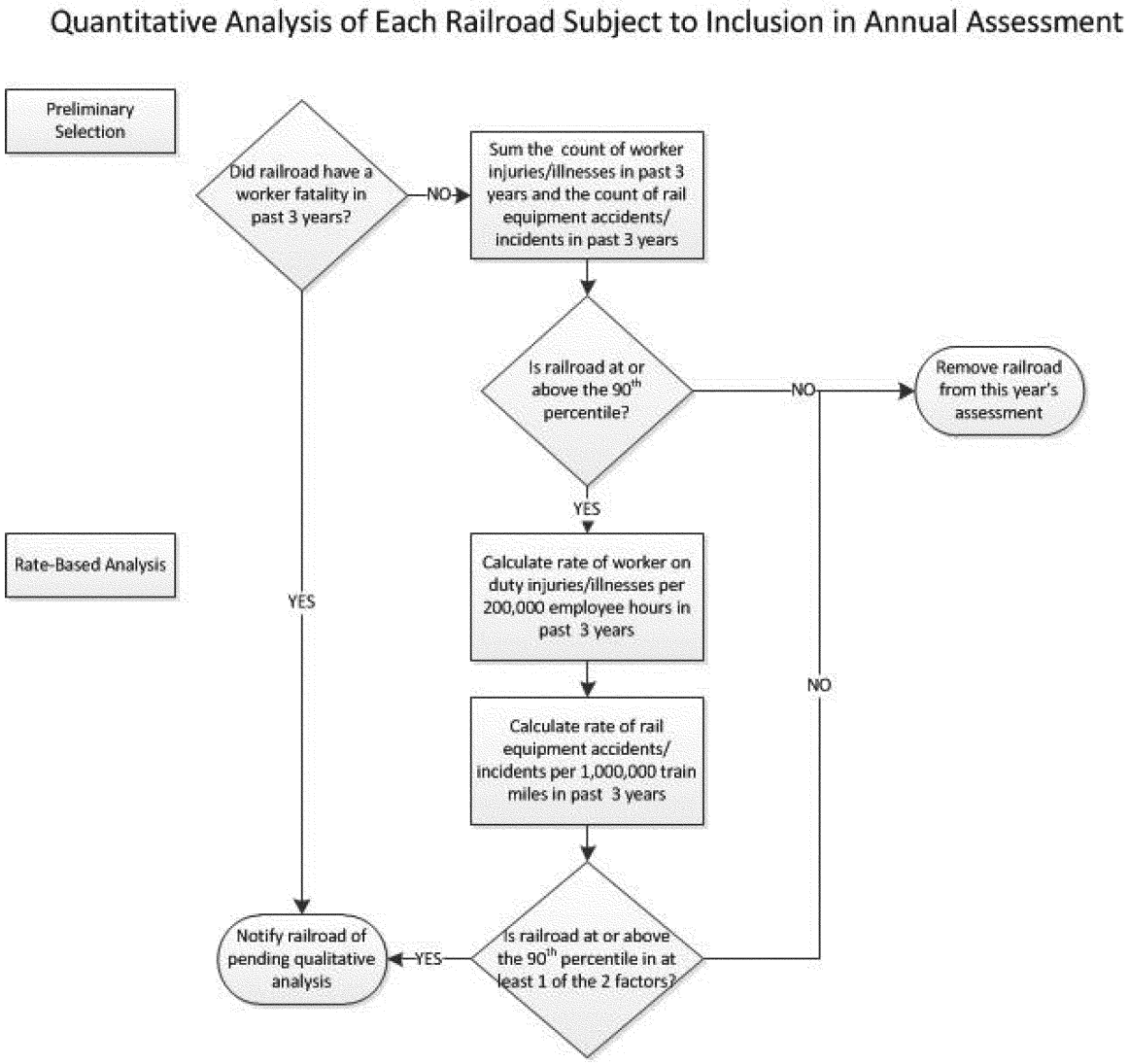
An individual commented supporting a previous individual comment submitted in response to the ANPRM, asserting a ''key metric for deciding if a non-Class I railroad has an 'inadequate safety record' . . . should be whether it transports the most dangerous hazmat cargoes through urban areas or sensitive environmental areas.'' The New Jersey Work Environment Council's comment shared this concern.

FRA does not believe that simply transporting dangerous hazardous materials through urban or sensitive environmental areas is a valid metric for determining whether a railroad has inadequate safety performance. Such operations only indicate a railroad's specific hazards and risks, and do not indicate whether a railroad is safely performing such operations. FRA's quantitative analysis will identify such railroads, however, if they have a worker on-duty fatality or a high number and rate of FRA reportable accidents/incidents, FRA reportable illnesses/injuries, and FRA violations (as calculated by the rule's methodology). Once the quantitative analysis identifies such a railroad, FRA can review factors such as the shipment of dangerous hazardous materials through urban or sensitive environmental areas as part of the qualitative analysis. For example, FRA has data regarding shippers of

[18] FRA's analysis estimated that approximately eight to nine railroads would be identified each year.

hazardous materials, commodity flows, and other GIS-related data that can be considered in the qualitative analysis. Additionally, the HHFT Final Rule establishes requirements regarding the routing of certain hazardous materials. FRA therefore concludes this final rule should not consider imposing an additional regulatory requirement upon railroads simply based on whether a railroad transports dangerous hazardous materials through urban or sensitive environmental areas.

To summarize, the below flow chart illustrates how the quantitative analysis will identify railroads for the qualitative assessment.



Paragraph (c) describes FRA's qualitative assessment of railroads the quantitative analysis identifies as possibly having inadequate safety performance. FRA made several non-substantive changes in this paragraph to replace passive voice with active voice. During the qualitative assessment, FRA will consider documentation from the railroad, comments from the railroad's employees, and any other pertinent information. This input will help FRA determine whether the quantitative analysis accurately identified a problem with the railroad's safety performance. Essentially, the qualitative assessment serves as a safety valve that helps FRA avoid determining a railroad demonstrates ISP merely because of one or more statistical outliers in FRA's data.

Paragraph (c)(1) states FRA will provide initial written notification to railroads identified in the threshold quantitative analysis as possibly having inadequate safety performance. Paragraph (c)(1)(i) further specifies that a notified railroad must inform its employees of FRA's notice within 15 days of receiving notification. A railroad must post this employee notification at all locations where a railroad reasonably expects its employees to report for work and have an opportunity to observe the notice. The railroad must continuously display the notice until 45 days following FRA's initial notice. A railroad must use other means to notify employees who do not have a regular on duty point to report for work, consistent with the railroad's standard practice for communicating with employees. Such a notification could take place by email, for example. The notification must inform employees that they may submit confidential comments to FRA regarding the railroad's safety performance, and must contain instructions for doing so. Any such employee comments must be submitted within 45 days of FRA's initial notice. FRA changed this

paragraph from the NPRM to add additional language specifying the railroad must also inform employees they must file any comments with the FRA Associate Administrator for Railroad Safety and Chief Safety Officer, 1200 New Jersey Avenue SE, Washington, DC 20590.

Likewise, paragraph (c)(1)(ii) provides railroads 45 days from FRA's initial notice to provide FRA documentation supporting any claim the railroad does not have inadequate safety performance. For example, if a fatality on railroad property was determined to be due to natural causes (such as cardiac arrest), or if an accident/incident was due to an act of God, the railroad's chief safety officer could provide a signed letter attesting to the facts and explaining why FRA should not find the railroad has inadequate safety performance. A railroad could also submit information regarding any extenuating circumstances of an incident or the severity of an injury (for example, a bee sting may not be as serious a safety concern as a broken bone, depending on the circumstances), or evidence that the railroad has already taken steps that effectively address a problem that led to the railroad being identified as possibly demonstrating inadequate safety performance. Further, although FRA has removed a railroad's FRA violation rate from the rated-based analysis, FRA may consider violations during the qualitative assessment (see below discussion of paragraph (c)(2)). FRA therefore still encourages a railroad to submit information regarding its FRA violations for consideration during the qualitative assessment. For example, FRA will consider explanations regarding FRA-issued violations and any mitigating action the railroad has taken to remedy the violations. FRA adopts this provision unchanged from the NPRM.

Paragraph (c)(2) describes the qualitative assessment of railroads the quantitative analysis identified. During the qualitative assessment, FRA will consider information a railroad or its employees provide under paragraph (c)(1) of this section and any other pertinent information. Even though FRA is removing a railroad's FRA violation rate from consideration in the quantitative analysis in response to concerns from AAR and ASLRRA (as discussed above), FRA does not agree with AAR and ASLRRA's contention that violations are ''meaningless'' when determining whether a railroad has inadequate safety performance. For example, frequent or severe violations of safety regulations can be an important indicator of a railroad's overall safety culture. This could be especially true in situations where FRA has issued the violations only after other attempts to correct the railroad's repeated non-compliance (*e.g.,* by issuing notices of defects or other written or verbal notices of non-compliance) have failed. Similarly, FRA also issues violations for one-time instances of non-compliance that are particularly egregious from a railroad safety perspective (*e.g.,* interference with a grade crossing system that results in an activation failure). In determining whether a railroad demonstrates inadequate safety performance, FRA considers it essential to consider violations to the extent they indicate either a poor safety culture or a one-time instance of non-compliance that is egregious or critical to safety. FRA is therefore adding language to paragraph (c)(2) clarifying that FRA may consider violations during the qualitative assessment.

FRA may communicate with the railroad during the qualitative assessment to clarify its understanding of any information the railroad submitted. Based upon the qualitative assessment, FRA will make a final determination regarding whether a railroad has inadequate safety performance no later than 90 days following FRA's initial notice to the railroad. Except for the added language regarding violations, FRA adopts this provision unchanged from the NPRM.

Paragraph (d) states FRA will provide a final notification to each railroad given an initial notification under paragraph (c) of this section, informing the railroad whether FRA has found it has inadequate safety performance. FRA has made a minor, non-substantive change to the NPRM's language to make the first sentence of this paragraph easier to read. Additionally, proposed paragraph (d) contained language addressing ISP railroad compliance, which FRA has moved to paragraph (e) of this section for organizational purposes. Consequently, there are non-substantive organizational changes to paragraph (e).

Paragraph (e)(1) contains language from proposed paragraph (d) of the NPRM, stating that an ISP railroad must develop and implement an RRP meeting the requirements of this rule and must submit an RRP plan meeting the filing and timing requirements of § 271.301. FRA has made minor changes to this language to streamline its content and avoid needlessly repeating the requirements of § 271.301. These changes do not affect the substance of the requirement.

Paragraph (e)(2) contains language from proposed paragraph (e) and states a railroad with inadequate safety performance must comply with the requirements of this rule for at least five years from the date FRA approves the railroad's RRP plan. FRA has made minor, non-substantive changes to streamline this language. As the NPRM explained, a five-year compliance period provides the minimum time necessary for an RRP to improve a railroad's safety performance. *See* 80 FR 10968 (Feb. 27, 2015). FRA expects a railroad with inadequate safety performance will take 36 months (3 years) following FRA plan approval to fully implement its RRP under § 271.225(a).[19] FRA does not expect an RRP, in itself, to improve a railroad's safety performance during this three-year implementation period, as a railroad will need this time to conduct a risk-based hazard analysis, prioritize risks, and develop mitigation strategies. A railroad will then begin applying mitigation strategies when it fully implements its RRP after three years. Once a railroad fully implements its RRP and begins applying mitigation strategies, the RRP will have at least two years to improve the railroad's safety performance by implementing mitigation measures and tracking their success. FRA bases this belief on an evaluation of an FRA Confidential Close Call Reporting System (C^3RS) demonstration site showing that C^3RS generated safety improvements two-and-a-half years after the railroad implemented the program.[20] *See* Ranney, J. and Raslear, T., ''Derailments decrease at a C^3RS site at midterm,'' FRA Research Results: RR12–04, April 2012, *available at http://www.fra.dot.gov/eLib/details/L03582.* The five-year compliance period therefore gives a railroad three years to fully implement its RRP and two years for a fully-implemented RRP to generate safety improvements. The two-year period after full implementation also provides FRA at least one opportunity

[19] FRA considered requiring a railroad with inadequate safety performance to comply with this rule for two years after submitting a notice to FRA demonstrating it had fully implemented its RRP. FRA concludes, however, that such a notice would impose an additional paperwork and cost burden on both the railroad and FRA. Rather, FRA believes most railroads will take three years to fully implement an RRP as § 271.225(a) allows.

[20] Specifically, the evaluation found the following safety improvements at the C^3RS demonstration site: (1) A 31-percent increase in the number of cars moved between incidents; (2) improved labor-management relations and employee engagement (*i.e.,* an improved safety culture); and (3) a reduction in discipline cases. *See* Ranney, J. and Raslear, T., ''Derailments decrease at a C3RS site at midterm,'' FRA Research Results: RR12–04, April 2012, *available at http://www.fra.dot.gov/eLib/details/L03582.*

to conduct an external audit of the railroad's fully-implemented RRP and to provide the railroad written results. FRA concludes, therefore, that the five-year compliance period is necessary to determine whether a railroad's fully-implemented RRP is generating safety improvements that are sustainable. FRA adopts this paragraph unchanged from the NPRM.

FRA is adding language in paragraph (f) establishing an appeals process for railroads that FRA determines demonstrate inadequate safety performance. AAR/ASLRRA commented urging FRA to establish an appeals process for railroads that the proposed methodology identifies as having inadequate safety performance. AAR/ASLRRA noted that other FRA regulations include such a process (*e.g.,* part 240—Qualification and Certification of Locomotive Engineers and part 242—Qualification and Certification of Conductors), and FRA has acknowledged such processes are fair and successful. AAR/ASLRRA specifically suggested that the process should ''allow neutral persons to review and provide a determination, which would enhance objectivity.'' AAR/ASLRRA did not provide a specific suggestion indicating who should be the ''neutral persons.''

FRA agrees including an appeals process for railroads determined to have inadequate safety performance would be fair. FRA therefore changed § 271.13 to add a process allowing railroads to petition the FRA Administrator for reconsideration of inadequate safety performance determinations under 49 CFR 211.7(b)(1), 211.56, and 211.59, which are procedures to appeal various FRA actions to the Administrator (*e.g.,* Railroad Safety Board decisions regarding petitions for waiver of safety rules under 49 CFR part 211, subpart C). These procedures are well-established and should be familiar to the railroad industry.

Providing a direct appeal to the Administrator is appropriate because FRA will have already created a record of the inadequate safety performance determination as part of the quantitative and qualitative analysis. This record will also include comments and documentation railroads and railroad employees have submitted to FRA as part of the qualitative assessment.[21] After reviewing the record, the Administrator may either affirm, modify, or revoke the determination. Using existing procedures for appealing inadequate safety performance determinations reduces both uncertainty and unnecessary duplication.

Paragraph (f)(1) states that a railroad wishing to appeal a final written ISP determination must file a petition for reconsideration with the Administrator. Paragraph (f)(1)(A) states a railroad must file the petition no later than 30 days after the date the railroad receives FRA's final written notice under paragraph (d) of this section, and paragraph (f)(1)(B) states a railroad must comply with the procedures in §§ 211.7(b)(1) and 211.57. Paragraph (f)(2) states FRA will process petitions under § 211.59.

Because FRA is including an appeals process in paragraph (f) of the final rule, FRA has moved proposed paragraph (f) from the NPRM to paragraph (g) in this final rule. At the end of the five-year period, paragraph (g) provides that the railroad may petition FRA for approval to discontinue compliance with this rule, and FRA will process the petition using the procedures for waivers in 49 CFR 211.41. While the NPRM merely referenced the waiver provisions of part 211 in general, FRA is specifying § 211.41 in the final rule to clarify that the railroad must follow the procedures for waivers of safety rules (and not other petition processes in part 211, such as petitioning for a rulemaking in § 211.11). Further, while the NPRM did not specify how FRA would process the petition, FRA also changed this language to clarify that FRA will process the petition under § 211.41. As a result, FRA also removed language in the NPRM stating that FRA will notify a railroad in writing whether or not the railroad must continue compliance with the rule. This language is unnecessary because § 211.41 contains provisions regarding what notification FRA must provide a railroad. Upon receiving a petition, FRA will evaluate the railroad's safety performance to determine whether the railroad's RRP has resulted in significant safety improvements, and whether these measured improvements are likely to be sustainable in the long term. FRA's evaluation will include a quantitative analysis as described in paragraph (b). FRA has added language to this paragraph clarifying that FRA will not automatically grant a petition to discontinue compliance if the quantitative analysis results do not meet the identification thresholds described for moving on to the qualitative analysis (although FRA would certainly consider such results). For all petitions, FRA will also examine qualitative factors and review information from FRA RRP audits and other relevant sources. This approach ensures that a railroad is not granted permission to discontinue compliance when its safety record has not substantively improved, but, rather, the rest of the railroad industry has become statistically less safe, thereby making the ISP railroad appear only comparatively safer. In such a scenario, FRA believes it will be appropriate to effectively increase the pool of ISP railroads by requiring continued compliance for ISP railroads that have not substantively improved their safety performance. While ASLRRA commented in response to DOT's regulatory review initiative that there was no performance benchmark for removal from mandatory ISP compliance, FRA believes that this approach—combining a new ISP analysis with an evaluation of whether the ISP railroad's RRP has generated long-term, sustainable safety benefits—provides a sufficient benchmark for judging whether an ISP railroad must continue RRP compliance.

Analysis of the railroad's safety performance to decide whether FRA should grant its petition will depend on the unique characteristics of the railroad and its RRP. Therefore, it is not possible to enumerate the types of data FRA will examine to evaluate a petition to discontinue compliance. In general, FRA will look at information it needs to determine whether there are real and lasting changes to the operational safety and organizational safety culture. The Safety Board will use staff recommendations and other information it deems necessary to make a final determination about whether granting a petition is in the interest of public safety. After completing the evaluation, FRA will notify the railroad in writing whether it will be required to continue compliance with this part. FRA will encourage a railroad to continue its RRP voluntarily even if FRA grants its petition to discontinue compliance with this part. If a railroad decides to continue its RRP after FRA grants its petition to discontinue compliance, FRA will consider the railroad a

[21] Because AAR/ASLRRA's comment specifically referenced the appeals processes of parts 240 and 242 (which govern locomotive engineer and conductor certification), FRA notes that the record created during the inadequate safety performance analysis parallels the record created during an administrative hearing under §§ 240.409 and 242.509. FRA does not believe it is necessary to establish a board similar to the Operating Crew Review Board (OCRB) to review these determinations before an appeal to the Administrator, as the OCRB only reviews railroad certification decisions under parts 240 and 242 and does not act in a fact-finding capacity. Unlike with locomotive engineer and conductor certification proceedings, there will be no railroad determination in the RRP context for such a board to review. FRA also believes incorporating too many layers of appeal would unduly slow down the inadequate safety performance determination process.

voluntarily-compliant railroad under § 271.15. This will continue application of § 271.11 to protect information the railroad continues to compile or collect under its voluntary RRP from discovery and admission as evidence in litigation. If a railroad decides not to continue with a voluntarily-compliant RRP meeting the requirements of this part, information it compiled or collected under the RRP will remain protected under § 271.11. However, § 271.11 will not protect any new information compiled or collected after the railroad discontinues its RRP.

Section 271.15—Voluntary Compliance

The RSIA provides that railroads not required to establish a railroad safety risk reduction program may nevertheless voluntarily submit for FRA approval a plan meeting the requirements of the statute. *See* 49 U.S.C. 20156(a)(4). Section 271.15(a) implements this language by permitting a railroad not otherwise subject to the rule to voluntarily comply by establishing and fully implementing an RRP that meets the requirements of the rule. While this paragraph in the NPRM said a voluntarily-compliant railroad ''could be subject to civil penalties for failing to comply with the requirements of this part,'' FRA is rephrasing this sentence and changing ''could'' to ''is'' in the final rule to make this language consistent with other provisions in FRA regulations discussing civil penalties (*See e.g.,* § 271.9 of this final rule). This change does not affect the substance of this paragraph. Because FRA otherwise adopts paragraph (a) unchanged from the NPRM, FRA is not repeating the NPRM's section-by-section analysis here but refers interested readers to the NPRM's discussion. *See* 80 FR 10969 (Feb. 27, 2015).

Paragraph (b) specifies that a voluntarily-compliant railroad must comply with this rule's requirements for a minimum period of five years, running from the date on which FRA approves the railroad's RRP plan. As with ISP railroads, the rule therefore provides a voluntarily-compliant railroad three years to fully implement an RRP under § 271.225(a) and two years following full implementation to realize RRP-related safety improvements. Further, as the NPRM and the above section-by-section analysis for § 271.13(e)(2) explain, a five-year period provides the minimum amount of time necessary for an RRP to have a substantive effect on a railroad's safety performance. *See* 80 FR 10969 (Feb. 27, 2015).

AAR/ASLRRA and ASLRRA both commented that a five-year compliance period was unnecessary and that FRA should require railroads to voluntarily comply only for two years, asserting small railroads can make changes quickly and efficiently. As explained above, a minimum five-year compliance period appropriately provides a voluntarily-compliant railroad three years to fully implement its RRP and two years following full implementation to realize safety improvements. Further, because there is a wide range of size among Class II and Class III railroads, FRA does not believe all voluntarily compliant railroads will be able to establish an RRP and achieve safety improvements in two years.[22]

An RRP is also an ongoing commitment to safety, not a program a railroad temporarily implements to address a specific problem and then abandons once the problem is fixed. Such an approach would make RRP another reactive program, instead of a proactive approach to improving railroad safety. Moreover, a railroad that volunteers to comply with the RRP rule, knowing such compliance must last five years, is making an important demonstration of that safety commitment. If a voluntarily-compliant railroad concludes that an RRP has either achieved the railroad's safety goals or is not producing safety benefits before the end of the five-year compliance period, the railroad could petition FRA for a waiver from this rule's requirements under part 211, subpart C's procedures for requesting waivers of safety rules.

The five-year compliance period also helps prevent situations in which a railroad will voluntarily comply for a few months or years only to selectively take advantage of this rule's information protections, abandoning the program once the railroad has achieved its information protection goals. If a railroad wishes to have this rule's information protection benefits, the railroad should earnestly commit to complying for a minimum of five years, which gives the railroad three years to fully implement its RRP and two years to realize safety improvements following full implementation.

Finally, FRA will expend agency time and resources in approving a voluntarily-compliant railroad's RRP plan and auditing the railroad's RRP. In return, FRA expects a voluntarily-compliant railroad to commit to complying with this rule for five years. Otherwise, FRA could expend agency resources for limited or even non-existent safety benefits.

Conversely, Labor Organizations I argued that FRA should require voluntarily-compliant railroads to comply with the rule permanently. A permanent compliance approach, however, could disincentivize voluntary compliance to the extent that no (or very few) railroads would ever volunteer. FRA therefore declines to require permanent, voluntary compliance.

The NPRM also requested public comment on whether FRA should allow railroads to voluntarily comply with an SSP final rule instead of an RRP final rule. No commenters responded to FRA's questions, and FRA is not including a voluntary SSP compliance provision in this final rule. FRA concludes that any such provision would properly belong in the SSP rule, not the RRP rule.

Paragraph (c) in the NPRM proposed that a voluntarily-compliant railroad could petition FRA to discontinue compliance with the rule after the minimum five-year compliance period. ASLRRA commented that the requirement to comply should terminate automatically, unless FRA determines otherwise. After reassessing proposed paragraph (c), FRA is concerned that the proposed approach would disincentivize voluntary compliance by making it more difficult for a voluntarily-compliant railroad to leave the program once it joins. Paragraph (c) of the final rule therefore provides that a voluntarily-compliant railroad may discontinue mandatory compliance with this rule after the five-year period by providing written notice to the FRA Associate Administrator for Railroad Safety and Chief Safety Officer. This approach will not negatively impact safety, because FRA will add the former voluntarily-compliant railroad to the pool of railroads FRA annually analyzes for inadequate safety performance. Some inefficiencies may occur if a former voluntarily-compliant railroad dismantles its RRP, but then must recreate the program if FRA determines that the railroad demonstrates inadequate safety performance. However, this scenario is unlikely for several reasons. First, the rule's information protections will be an incentive for a railroad to continue compliance, as the protections will not apply to information that a railroad compiles or collects for non-RRP purposes. This incentive will lower the number of voluntarily-compliant railroads that decide to discontinue mandatory compliance. Second, a voluntarily-compliant railroad will not discontinue compliance if it reasonably

[22] FRA also notes that the STB classifies railroads based on revenue, not system size or complexity. *See* 49 CFR 1201.1–1. Further, revenue alone may not be an adequate indicator of how quickly a railroad could implement an RRP.

believes FRA will thereafter determine that the railroad demonstrates inadequate safety performance because, if FRA then found the railroad had inadequate safety performance, the railroad could discontinue compliance only if FRA granted its petition to discontinue under § 271.13(g). Finally, FRA believes many voluntarily-compliant railroads will comply indefinitely with the RRP rule because they will realize the safety benefits an RRP generates. Once a voluntarily-compliant railroad implements an RRP and begins to realize its safety benefits, it is unlikely the railroad would dismantle its program.

Paragraph (d) provides that the information protection provisions of § 271.11 apply to information a voluntarily-compliant railroad compiles or collects under a voluntarily-compliant RRP meeting the requirements of this rule. As discussed in the section-by-section analysis for § 271.11, voluntary risk reduction programs (for example, programs generated as part of a Short Line Safety Institute) must fully comply with this rule for the information generated to be protected from discovery and use as evidence in litigation. FRA changed this provision from the NPRM to include a reference to § 271.301(b)(4)(ii), discussed further below, which provides that the § 271.11 information protections will apply to a voluntarily-compliant railroad starting on the day the railroad notifies FRA it intends to file an RRP plan for review and approval. FRA also modified this provision by removing the word ''only,'' which could have implied that § 271.11 applied only to voluntarily-compliant railroads.

ASLRRA generally commented that ''FRA has proposed requirements designed to limit the number of railroads that comply voluntarily. The ASLRRA submits that any requirement to limit the number of small railroads that comply voluntarily is antithetical to the letter and spirit of the RSIA.'' ASLRRA's comment is unclear to FRA, as FRA does not believe § 271.15 establishes requirements to limit the number of railroads that comply voluntarily. To the extent ASLRRA's comment means the five-year compliance period would disincentivize voluntary participation, FRA refers to the above discussion of why FRA believes this compliance period is necessary. FRA also believes that this rule's information protections provide a reasonable incentive for voluntarily-compliant railroads, even with the five-year compliance period.

Subpart B—Risk Reduction Program Requirements

Subpart B contains the basic RRP elements the rule requires. The rule provides a railroad significant flexibility in developing and implementing an RRP.

Section 271.101—Risk Reduction Programs

Section 271.101 contains general RRP requirements. Paragraph (a) requires railroads to establish and fully implement an RRP meeting the requirements of this rule. Except for the minor changes discussed below, FRA adopts paragraph (a) unchanged from the NPRM. FRA therefore refers interested readers to the NPRM's discussion. *See* 80 FR 10969 (Feb. 27, 2015).

As proposed in the NPRM, the third sentence of paragraph (a) stated, ''An RRP is not a one-time exercise, but an ongoing program that supports continuous safety improvement.'' FRA has removed the phrase ''not a one-time exercise, but'' in the final rule, so the sentence now reads, ''An RRP is an ongoing program that supports continuous safety improvement.'' This change does not affect the substantive meaning of the sentence (which is to indicate the ongoing nature of an RRP) and was made solely to streamline the regulatory language.

FRA also changed paragraph (a) to include a sentence clarifying that a railroad must design its RRP to promote and support a positive safety culture at the railroad. Although the NPRM did not propose this specific language, FRA believes promoting a positive safety culture is intrinsic to SMS programs like RRP, and improving a railroad's safety culture was extensively discussed in the NPRM. *See id.* at 10952, 10953, 10968, 10971, and 10973. A railroad must also identify and analyze its safety culture under § 271.105(a), describe its safety philosophy and safety culture under § 271.203(b)(1), and describe how it promotes improvements to its safety culture under § 271.203(b)(2). The added language reflects that an important component of an RRP is an improved safety culture. Further, the SSP NPRM proposed identical language, which is included in the SSP rule, and FRA is including this language in paragraph (a) to promote consistency between the two rules. *See* 77 FR 55403 (Sept. 7, 2012) and 81 FR 53878, 53897 (Aug. 12, 2016). FRA inadvertently omitted including this language in the RRP NPRM.

Paragraphs (a)(1) through (5) list necessary components that an RRP must contain, including: (1) A risk-based hazard management program (described in § 271.103); (2) a safety performance evaluation component (described in § 271.105); (3) a safety outreach component (described in § 271.107); (4) a technology analysis and technology implementation plan (described in § 271.109); and (5) RRP implementation and support training (described in § 271.111). FRA adopts these paragraphs unchanged from the NPRM.

Paragraph (a)(6) references a component the NPRM did not specifically include: Involvement of railroad employees in the establishment and implementation of an RRP under § 271.113. The section-by-section analysis for § 271.113 discusses the substance of this additional component in detail.

Paragraph (b) requires a railroad to support its RRP with an FRA-approved RRP plan meeting subpart C requirements. FRA adopts paragraph (b) unchanged from the NPRM. Proposed paragraph (c) of the NPRM addressed railroads subject to the RRP rule that host passenger train service for passenger railroads subject to the requirements of the SSP rule. Under § 270.103(a)(2) of the SSP rule, a passenger railroad must communicate with each host railroad to coordinate the portions of its SSP plan applicable to the host railroad. *See* 81 FR 53897 (Aug. 12, 2016). Paragraph (c) of the NPRM proposed requiring a host railroad, as part of its RRP, to participate in this communication and coordination with the passenger railroad.

APTA commented that proposed paragraph (c) ''aspires to communication and cooperation, but provides no framework for accomplishing either and no standard by which to measure either.'' FRA does not agree that this provision requires additional framework or standards. Because no two arrangements between a passenger railroad and a host railroad will be the same, a passenger railroad and host railroad should have the flexibility to communicate and cooperate in the manner best suited to their particular operations. However, FRA made minor changes to proposed paragraph (c) for clarity. FRA also designated proposed paragraph (c) as paragraph (c)(1). FRA does not intend these changes to affect the substance of the provision.

In response to DOT's regulatory review initiative, VRE commented expressing concern that it may be subject to enforcement action if, despite attempting in good faith to communicate with its host railroads (which include CSX Transportation,

Norfolk Southern Corporation, and Amtrak) as the SSP rule requires, its host railroads did not cooperate in producing data or other information necessary for VRE's SSP. *See* DOT–OST–2017–0069–2405. Paragraph (c) addresses VRE's concern, as it specifically requires an RRP railroad to communicate and coordinate with a tenant SSP railroad as required by the SSP final rule. A host RRP railroad that does not participate in this communication and coordination could then be subject to FRA enforcement action under the RRP final rule.

FRA also added a paragraph (c)(2) to the final rule, requiring a host railroad to incorporate its communication and coordination with the SSP railroad into its own RRP. This language ensures a railroad's SSP communication is not completely isolated from the railroad's own RRP. Because RRP and SSP are systemic programs intended to promote analysis and proactive mitigation measures, communication and coordination between a railroad's RRP and SSP activities will improve railroad safety.

In paragraph (d) of the NPRM, FRA proposed requiring a railroad to ensure persons utilizing or performing a significant safety-related service on its behalf support and participate in the railroad's RRP. The NPRM identified such persons as host railroads, contract operators, shared track/corridor operators, or other contractors. AAR/ASLRRA commented that the term ''utilize'' could mean anyone interested in railroad safety, including passengers and the general public. Although AAR/ASLRRA indicated they were not concerned with the substance of the provision, they recommended that FRA remove the term ''utilize.''

FRA agrees with AAR/ASLRRA that paragraph (d) should not be interpreted to require a railroad to ensure passengers or the general public support and participate in the railroad's RRP as persons ''utilizing'' significant safety-related services. FRA's intent was to address persons who utilize a railroad's significant safety-related services on a routine or systemic basis to conduct railroad operations, such as a passenger railroad that operates over an RRP railroad's track and utilizes its dispatching service. FRA has, therefore, changed the language of this provision to clarify its requirements and reflect FRA's original intent. Paragraph (d) of the final rule first references § 271.205(a)(3), which requires a railroad's RRP plan to identify persons that enter into a contractual relationship with the railroad to either perform significant safety-related services on the railroad's behalf or to utilize significant safety-related services the railroad provides for railroad operations purposes. The changed language then clarifies the term ''utilize'' in two ways.

First, the relationship between the railroad and the person utilizing its significant safety-related services must be contractual. This language ensures there is a formalized agreement between the railroad and the person regarding the significant safety-related service. With the formalized agreement, the duties of the contractor will be clear and, therefore, the extent to which they are performing or utilizing significant safety-related services of the railroad will be clear as well. This language clarifies that this section does not require a railroad to ensure the general public (or any other entity with only an interest in the safe operation of a railroad as a matter of due course (for example, schools or residents located near an RRP railroad's track)) supports and participates in the railroad's RRP.

Second, the final rule's language clarifies that the person must be utilizing the railroad's significant safety-related services to conduct railroad operations. For example, if a railroad contracts with a company to perform bridge maintenance, that company provides a significant safety-related service to the railroad on behalf of the railroad. If during the bridge maintenance the company uses the railroad's roadway worker protection, that company is then also utilizing a significant safety-related service (roadway worker protection) provided by the railroad. A railroad does not have to identify persons providing or utilizing significant safety-related services for purposes unrelated to railroad operations, such as railroad passengers or motor vehicle drivers who benefit from a highway-rail grade crossing warning system. The SSP final rule contains similar language in § 270.103(d)(2). *See* 81 FR 53897 (Aug. 12, 2016).

FRA also added language clarifying that a railroad must identify such a person even if the person is not otherwise required to comply with this rule (for example, a tourist railroad that operates over an RRP railroad's track). The final sentence of paragraph (d) is also essentially the same as the NPRM, and requires a railroad to ensure the identified persons support and participate in the railroad's RRP.

Section 271.103—Risk-Based Hazard Management Program

Except for changing a reference to § 271.301(b) in the proposed rule to § 271.301(d) to account for organizational changes in § 271.301, FRA adopts this section, which contains the requirements for each risk-based hazard management program (HMP), unchanged from the NPRM. FRA is therefore not repeating the NPRM's section-by-section analysis in this final rule, but refers interested readers to the NPRM's discussion. *See* 80 FR 10970–10971 (Feb. 27, 2015). FRA is, however, discussing comments it received in response to the proposed requirements of this section, although FRA is not making changes in response.

AAR/ASLRRA commented on proposed paragraph (b). As proposed under paragraph (b), a railroad must conduct a risk-based hazard analysis as part of its risk-based HMP and specified that, at a minimum, a risk-based hazard analysis must address the following components of a railroad's system: Infrastructure; equipment; employee levels and work schedules; operating rules and practices; management structure; employee training; and other areas impacting railroad safety that are not covered by railroad safety laws or regulations or other Federal laws or regulations. AAR/ASLRRA commented that FRA should omit the reference to employee levels and work schedules because FRA carved fatigue management plans out for treatment in the separate FMP rulemaking. Thus, they conclude this language is not appropriate and should be removed.

FRA disagrees with AAR/ASLRRA because the language ''employee levels and work schedules'' may encompass issues unrelated to fatigue the FMP rulemaking will not address. For example, whether a railroad has a sufficient number of track inspectors for a certain territory may involve a question of employee levels, but not necessarily fatigue.

As proposed under paragraph (c) of the NPRM, a railroad must design and implement mitigation strategies that improve safety as part of its risk-based HMP, although the NPRM also clarified it was not defining a level or risk that railroad's risk-based HMP must target. *See* 80 FR 10971 (Feb. 27, 2015). FRA observed, however, that FRA's Passenger Equipment Safety Standards require passenger railroads, when procuring new passenger cars and locomotives, to ensure fire considerations and features in the equipment design reduce the risk of personal injury caused by fire to an acceptable level using a formal safety methodology such as MIL–STD–882. *See* 80 FR 10971 (Feb. 27, 2015) (*citing* 49 CFR 238.103(c)). FRA also noted passenger railroads operating Tier II passenger equipment must eliminate or

reduce risks posed by identified hazards to an acceptable level. *See Id.* (*citing* 49 CFR 238.603(a)(3)). FRA specifically requested comment on whether a final RRP rule should define levels of risks a railroad's risk-based HMP must target. *Id.*

Only AAR/ASLRRA commented in response, urging FRA not to define levels of risk railroads should target.[23] In support, AAR/ASLRRA distinguished the two part 238 provisions FRA cited from the proposed RRP rule, observing that the part 238 provisions involve risks associated with equipment design or operation, not risks associated with an entire railroad system. AAR/ASLRRA therefore observed it is not clear how the level of railroad-wide risk could be determined, given the number of component hazards and risks involved. AAR/ASLRRA also noted the cited part 238 provisions require reduction of risk to an acceptable level and refer to the methodology in MIL–STD–882, which requires reduction of risk to the lowest acceptable level within the constraints of cost, schedule, and performance, arguing these provisions themselves do not define acceptable or unacceptable levels of risk, but rather exhort actors to reduce risk to the lowest acceptable level, all things considered. AAR/ASLRRA assert that any additional requirement defining risk levels or resembling MIL–STD–882 would only add process, not substance. Having considered these comments, FRA clarifies that neither § 271.103 nor any other section in this final rule defines a level of risk a railroad should target.

An individual also commented generally that an RRP final rule should require fitness-for-duty standards and railroads must do more to monitor and prevent human performance lapses leading to train collisions and derailments. The individual suggested that instead of using inward-facing cameras to monitor and enforce rules, railroads should utilize inward-facing cameras with facial monitoring software to apply train brakes when operating personnel are falling asleep or otherwise inattentive. FRA declines to incorporate these suggestions because they address specific mitigations measures for specific railroad safety risks, and therefore are inappropriate for the process-oriented, performance-based nature of this final rule.

[23] AAR/ASLRRA's comment indicated that they were responding to proposed § 271.103(e). Because the NPRM did not contain a § 271.103(e), however, FRA assumes that AAR/ASLRRA's comment was in response to proposed paragraph (c) and FRA's solicitation of public comment.

Section 271.105—Safety Performance Evaluation

This section contains requirements for safety performance evaluations. Safety performance evaluation is a necessary part of a railroad's RRP because it determines whether the RRP is effectively reducing risk. It also monitors the railroad's system to identify emerging or new risks. The following are examples of changes to a railroad's system that may constitute a new or emerging risk: (1) A change in operating rules; (2) implementation of new technology, or (3) a reduction in crew staffing levels. Safety performance evaluation is essential for ensuring that a railroad's RRP is an ongoing process, and not merely a one-time exercise.

Except for paragraph (a) and a minor editorial change in paragraph (c), discussed below, FRA adopts this section unchanged from the NPRM. FRA is therefore not repeating the NPRM's section-by-section analysis in this final rule and refers interested readers to the NPRM's discussion. *See* 80 FR 10971 (Feb. 27, 2015). FRA also discusses comments it received in response to proposed paragraph (b)(5), but makes no changes based on those comments.

In addition to requiring a railroad to develop and maintain ongoing processes and systems for evaluating the safety performance of the railroad's system, paragraph (a) in the NPRM proposed requiring a railroad to develop and maintain processes and systems for measuring its safety culture. AAR/ASLRRA commented in response that section 20156 does not require a railroad to measure its safety culture as FRA proposed in this section and in § 271.213, discussed below. They argued the RSIA did not require a railroad to measure safety culture because it is hard to do so effectively and reliably, and culture can be described and evaluated, but not be meaningfully quantified. According to AAR/ASLRRA, each railroad is different, and their cultures and the ways those cultures present in the workplace are different. Further, as an RRP matures, they argued the approach each railroad takes to assessing its safety culture may change. AAR/ASLRRA specifically suggested that FRA should leave to each railroad the decisions regarding how to evaluate, assess, and support its safety culture without prescribing generation of measurement data.

Contrary to AAR/ASLRRA's comment, FRA did not intend proposed paragraph (a) to require a specific data-driven and quantifiable measurement of a railroad's safety culture. As the NPRM explained, a railroad could measure its safety culture by surveying employees and management to establish an initial baseline safety culture, and then comparing the initial baseline to subsequent surveys. *See* 80 FR 10971 (Feb. 27, 2015). The NPRM further clarified FRA would give a railroad substantial flexibility to decide which safety culture measurement best fit the organization—for example, a survey or other instrument that has been validated and proven to correlate with safety outcomes (*i.e.,* the survey or other instrument has been studied to determine whether it reliably and repeatedly measures what it intends to measure). FRA's primary concern would be to ensure the selected measurement provided a way to demonstrate that an improvement in the safety culture would reliably lead to a corresponding improvement in safety. *Id.* This approach gives a railroad sufficient flexibility to measure its safety culture in a manner that works best for the railroad, as AAR/ASLRRA urge.

In response to AAR/ASLRRA's comment, instead of the term ''measuring,'' this section of the final rule uses the phrase ''identifying and analyzing,'' which comes directly from section 20156(c) of the statutory mandate. A railroad will still have the flexibility to decide how to identify and analyze its safety culture if the tools the railroad uses provide a way to connect improvements in safety culture to corresponding improvement in safety.

Labor Organizations I also commented on how a railroad could measure safety culture. Referencing the FAA and ''Weick and Sutcliffe,'' Labor Organizations I noted that traits of a health safety culture can be identified within High Reliability Organizations. Labor Organizations I urged FRA to establish criteria mandating that railroad RRPs adhere to standards proven in other industries where the principles of safety are the same despite operational or other differences.

FRA is not adopting specific standards regarding how a railroad must identify and analyze its railroad safety culture. Although various such standards exist, FRA is unaware of a universal standard for safety culture this final rule could adopt. Further, the final rule contains a DOT-wide definition of safety culture, discussed in the section-by-section analysis for § 270.5, which provides substance for the meaning of safety culture. Even if there was a universal safety culture standard fitting every railroad that FRA could mandate, doing so would codify today's safety culture standards into the rule, requiring an amendment process every

time such standards advanced or progressed. FRA anticipates the understanding of safety culture will change as time progresses and does not want to restrict railroads to using today's standards for tomorrow's analysis. FRA is therefore declining to mandate specific safety culture standards in the final rule, but is instead implementing an approach where a railroad must describe in its RRP plan how it will identify and analyze its safety culture, noted above.

Paragraph (b)(5) in the NPRM proposed that one of the sources a railroad must establish to monitor safety performance is a reporting system through which employees can report safety concerns (including, but not limited to, hazards, issues, occurrences, and incidents) and propose safety solutions and improvements. The NPRM explained this would not require a railroad to establish an extensive program like FRA's C³RS, although FRA specifically requested public comment elsewhere in the NPRM on the extent to which programs like C³RS might be useful to develop an RRP or as a component of an RRP. *See* 80 FR 10954 and 10971 (Feb. 27, 2015). Labor Organizations I commented in response that the confidentiality component of C³RS programs may make them difficult to contain within the confines of an RRP. Specifically, Labor Organizations I urged separation between RRP and C³RS because they believe C³RS confidentiality is incompatible with the level of description necessary to conform to this paragraph's requirements. Labor Organizations I also specifically commented that C³RS programs should not simply be re-branded to comply with the RRP requirements.

FRA both disagrees and agrees with Labor Organization I's comment. FRA disagrees with Labor Organization I because a railroad could incorporate a C³RS program into its RRP. FRA also disagrees with Labor Organizations I that the confidentiality associated with C³RS programs may not be compatible with the description needed for this requirement. Even though C³RS reports are de-identified to remove information that may identify the reporter or other employees involved, sufficient information will likely still be included to allow a railroad to analyze the general risks and hazards presented by the report. Further, if a railroad wanted to obtain more information, it could establish a second reporting system to supplement C³RS for employees who are not concerned about maintaining confidentiality. FRA agrees with Labor Organizations I, however, that a railroad cannot comply with an RRP final rule simply by re-branding a C³RS program as an RRP. While C³RS can be part of an RRP, a railroad must go further to meet the requirements of this final rule.

An individual also commented generally that FRA should require all railroads to implement a C³RS program as part of their RRPs. FRA is not implementing this suggestion because it is not in the voluntary spirit of the C³RS program. An effective C³RS depends on the trust and voluntary participation of all parties—qualities that would lose their meaning if FRA mandated C³RS for all RRP railroads.

The final change FRA made to this section is replacing the phrase ''For the purpose of assessing'' with the phrase ''To assess'' in paragraph (c). FRA made this change to streamline paragraph (c) and does not intend to affect its meaning.

Section 271.107—Safety Outreach

FRA adopts this section, with requirements on the safety outreach component of an RRP, unchanged from the NPRM. FRA is therefore not repeating the NPRM's section-by-section analysis in this final rule, but refers interested readers to the NPRM's discussion. *See* 80 FR 10971–10972 (Feb. 27, 2015).

Section 271.109—Technology Analysis and Technology Implementation Plan

This section implements the RSIA requirement that an RRP include a technology analysis and a technology implementation plan. *See* 49 U.S.C. 20156(e). Except for a PTC deadline revision discussed below and changing an incorrect reference in the proposed rule from § 271.13(e) to § 271.13(d), FRA adopts this section unchanged from the NPRM, but is addressing comments received in response to this section in the NPRM. FRA is therefore not repeating the NPRM's section-by-section analysis in this final rule but refers interested readers to the NPRM's discussion. *See* 80 FR 10972 (Feb. 27, 2015).

Paragraph (b) in the NPRM proposed requiring a railroad to conduct a technology analysis evaluating current, new, or novel technologies that may mitigate or eliminate hazards and the resulting risks identified through the risk-based hazard management program. At a minimum, proposed paragraph (b) stated a technology analysis must consider processor-based technologies, PTC systems, electronically-controlled pneumatic (ECP) brakes, rail integrity inspection systems, rail integrity warning systems, switch position monitors and indicators, trespasser prevention technology, and highway-rail grade crossing warning and protection technology.

AAR/ASLRRA commented in response that FRA should not require a railroad to address PTC systems and ECP brakes, asserting that other rulemakings performed a cost/benefit analysis for PTC and ECP brakes. AAR/ASLRRA argued that requiring railroads to perform the same analyses again as part of complying with the rule would be meaningless and inappropriate.

Because the RSIA mandates this requirement, FRA is promulgating paragraph (b) unchanged. In addition, this section requires a railroad to only evaluate the safety impact, feasibility, and costs and benefits of PTC systems and ECP brakes, and does not necessarily require implementation. This analysis will differ from railroad to railroad, and therefore is not directly comparable to FRA's cost/benefit analysis in other rulemakings.

Paragraph (d) provides that, except as required by 49 CFR part 236, subpart I (Positive Train Control Systems), if a railroad decides to implement a PTC system as part of its technology implementation plan, the railroad shall set forth and comply with a schedule for implementation of the PTC system consistent with the deadlines in the Positive Train Control Enforcement and Implementation Act of 2015 (PTCEI Act), Public Law 114–73, 129 Stat. 576–82 (Oct. 29, 2015), and 49 CFR 236.1005(b)(7). The NPRM proposed that the railroad would have to implement the PTC system by December 31, 2018, which was consistent with 49 U.S.C. 20156(e)(4)(B). However, Congress subsequently passed the PTCEI Act, and FRA has changed paragraph (d) to reflect the changes to PTC implementation deadlines set forth in the Act. This paragraph does not, in itself, require a railroad to implement a PTC system. In the NPRM, FRA sought comment on whether a railroad electing to implement a PTC system would find it difficult to meet the December 31, 2018 implementation deadline. If so, FRA invited comment as to what measures could be taken to assist a railroad struggling to meet the deadline and achieve the safety purposes of the statute. FRA received two comments in response to this request. AAR/ASLRRA commented that the 2018 deadline is unrealistic even for the Class I railroads. Labor Organizations I and an individual commented that FRA should not extend the 2018 deadline.[24]

[24] Labor Organizations I identified a December 31, 2015 PTC deadline. As both the NPRM and section

Continued

FRA recognizes the challenges associated with implementing a PTC system; however, FRA also recognizes that PTC is a technology that a railroad may seek to implement to eliminate or mitigate hazards and the resulting risks. Therefore, the regulation provides railroads the flexibility to decide whether they want to implement a PTC system as part of their technology analysis and implementation plan; if they do so, they must comply with an implementation schedule consistent with the deadlines in the PTCEI Act. The SSP final rule establishes the same deadline in § 270.103(r)(5). *See* 81 FR 53877 (Aug. 12, 2016).

Section 271.111—Implementation and Support Training

This section requires a railroad to provide RRP training to each employee who has significant responsibility for implementing and supporting the railroad's RRP. Except for changes made to clarify paragraphs (a) and (b) discussed below, FRA adopts this section unchanged from the NPRM but is addressing comments received in response to this section in the NPRM. FRA is therefore not repeating the NPRM's section-by-section analysis in this final rule but refers interested readers to the NPRM's discussion. *See* 80 FR 10972–10973 (Feb. 27, 2015).

Proposed paragraph (a) specified the employees a railroad must train includes an employee of any person a railroad's RRP plan identified under § 271.205(a)(3) when that employee has significant responsibility for implementing and supporting the railroad's RRP. *See* 80 FR 10972 (Feb. 27, 2015). For reasons explained in the section-by-section analysis for § 271.101(d) above, FRA changed this provision to clarify which employees a railroad must identify under § 271.205(a)(3). FRA does not intend these changes to affect the substance of the proposed rule.

Proposed paragraph (b) specified a railroad must keep a record of training conducted under this section and update that record as necessary. FRA has included language in this paragraph of the final rule clarifying a railroad must make these records available for inspection and copying upon request to FRA or State railroad safety inspectors.

AAR/ASLRRA commented the proposed training requirement is an unnecessary and inappropriate overreach that belies the performance-based approach to rulemaking FRA claims the proposed rule effects. AAR/ASLRRA agreed with FRA's statement in the NPRM that the training requirement would apply to personnel not involved in operational duties and not directing or supervising those who do have such duties. However, AAR/ASLRRA asserted it would require a railroad to train employees including the chief safety officer of the railroad, and his or her direct reports and requiring employees at that level to submit to training implies they do not know or care how to do their jobs. AAR/ASLRRA suggest that if railroads determine effective implementation of their RRP would be aided by training certain employees, the content and timing of such training is a matter appropriately left to the railroads.

Conversely, Labor Organizations I commented the NPRM proposed highly limited requirements for railroads to train their employees to understand and participate in the RRP process. They argue there needs to be continued vigilant attention to risk reduction throughout the workforce to ensure there is full understanding of the dynamics of the issues in the workplace. Labor Organizations I suggested FRA should consider broadening the scope of the proposed training.

FRA is implementing the proposed training requirement in this final rule substantively unchanged, without adding additional requirements. FRA disagrees with AAR/ASLRRA that this training is unnecessary, as railroad employees, including high-level employees, may not know how to implement an RRP that complies with the specific requirements of this final rule, even if the employees are otherwise familiar with safety risk reduction programs. FRA also disagrees with Labor Organizations I that the final rule should expand the scope of the training.

Section 271.113—Involvement of Railroad Employees

This section requires a railroad's RRP to involve the railroad's directly affected employees in the establishment and implementation of an RRP.

Paragraph (b) explains how a railroad should involve its directly affected employees, clarifying that a railroad must have a process for involving railroad employees when identifying hazards, developing and implementing mitigation strategies, conducting internal annual assessments, or otherwise performing actions required by this part. A railroad could involve its directly affected employees by including appropriate labor representatives or other employees on hazard management teams and by employee involvement in conducting RRP outreach.

While the NPRM did not specifically propose this component, employee involvement is an important component of a successful RRP. As the NPRM stated, an RRP encourages a railroad and its employees to work together to proactively identify hazards and to jointly determine what action to take to mitigate or eliminate the associated risks. *See* 80 FR 10950 (Feb. 27, 2015). While the NPRM contained provisions addressing railroad-employee consultation on the contents of a railroad's RRP plan, it did not specify that a railroad must involve its directly affected employees in subsequent implementation of its RRP plan. Nonetheless, FRA did not intend that a railroad could comply with the RRP plan consultation process requirements in § 271.207 and then not involve its directly affected employees in any aspect of its RRP once FRA approves the plan. FRA does not believe that is consistent either with the collaborative and proactive nature of risk reduction or Congress' intent in requiring railroads to consult with directly affected employees on the contents of the railroad's RRP plan. FRA is therefore expressly including this section in the final rule. FRA is characterizing this requirement as employee ''involvement'' instead of ''consultation'' to avoid confusion between this section and the requirements for RRP plan consultation in § 271.207. These are distinct concepts because this section's involvement requirement will last through the duration of the railroad's RRP, while the § 271.207 plan consultation process requirement is satisfied when a railroad uses good faith and best efforts to consult with its directly affect employees on its RRP plan and when FRA approves the railroad's submitted plan.

FRA further believes this involvement requirement will improve employee engagement in the railroad's RRP, thereby improving employee performance, safety culture, and railroad safety. *See generally* Wojick, Tom, Case: Engagement, Safety & Quality in Chemical Manufacturing, Oct. 29, 2013, *available at http://www.6seconds.org/2013/10/29/case-engagement-safety-quality/.* Additionally, this requirement will lead to improvements in employee psychology and behavior, which are important components of safety culture. *See generally* Arendt, Don, Federal Aviation Administration, A Model of Organizational Culture, Dec. 2008,

20156(e)(4)(B) state that the deadline is December 31, 2018, FRA assumes that Labor Organizations I intended to reference the 2018 deadline, and that reference to a 2015 deadline was an unintended mistake.

available at http://www.faa.gov/about/initiatives/sms/reference_library/links/media/organizational_culture_model.pdf.

Subpart C—Risk Reduction Program Plan Requirements

Subpart C contains requirements for RRP plans.

Section 271.201—General

This section requires a railroad to adopt and implement its RRP through a written RRP plan FRA has reviewed and approved under the requirements of subpart D. Because FRA adopts this provision unchanged from the NPRM, FRA is not repeating the NPRM's section-by-section analysis here but refers interested readers to the NPRM's discussion. *See* 80 FR 10973 (Feb. 27, 2015).

Section 271.203—Policy, Purpose and Scope, and Goals

This section contains requirements for policy, purpose and scope, and goals statements for an RRP plan. Except for moving a provision the NPRM proposed in paragraph (b)(4) to § 271.205(a)(4), as discussed below, this section remains unchanged. FRA is therefore not repeating the NPRM's section-by-section analysis here but refers interested readers to the NPRM's discussion. *See* 80 FR 10973–10974 (Feb. 25, 2017). FRA is otherwise addressing a comment received in response to this section in the NPRM, but is making no changes in response.

Paragraph (a) in the NPRM proposed requiring an RRP plan to include a policy statement endorsing the railroad's RRP signed by the chief official of the railroad (*e.g.,* Chief Executive Officer). AAR/ASLRRA commented FRA should require the railroad's Chief Safety Officer to sign the policy statement, as the RRP Working Group had proposed. AAR/ASLRRA further argued the proposed requirement also departs from section 20156(b), which specifies the chief official responsible for safety shall certify the contents of the program are accurate and the railroad will implement the contents of the plan. AAR/ASLRRA also asserted the chief official for safety will be more familiar with the details of the RRP than the chief official of the railroad and therefore is the more appropriate person to sign the policy statement.

FRA has not departed from the RSIA requirements because § 271.301(c)(1) of the final rule requires the railroad's chief official for safety to sign the RRP plan and certify the contents of the RRP plan are accurate and the railroad will implement the contents of the plan. This substantively mirrors the language in section 20156(b). Paragraph (a) of this section, however, requires the chief official at the railroad to sign the RRP policy statement, not the entire RRP plan. Prior experience with effective risk management programs has demonstrated to FRA how important the active involvement of the highest railroad officials is to improving safety and safety culture. Therefore, FRA determined the chief official at the railroad must sign the RRP policy statement.

Paragraph (b)(4) in the NPRM proposed requiring an RRP plan's purpose and scope statement to describe how any person that utilizes or provides significant safety-related services to a railroad (including host railroads, contract operators, shared track/corridor operators, or their contractors) will support and participate in the railroad's RRP. Upon review of the NPRM, FRA believes this provision belongs more appropriately in the § 271.205 requirements regarding an RRP plan's system description. FRA has therefore moved this provision to § 271.205(a)(4), and the section-by-section analysis for that section will discuss this provision further.

Section 271.205—System Description

This section requires an RRP plan to include a statement describing the characteristics of the railroad system. Except for changes made to clarify paragraph (a)(3) and language moved from § 271.203(b)(4) to paragraph (a)(4) of this section, discussed below, FRA adopts this section unchanged from the NPRM. FRA is therefore not repeating the NPRM's section-by-section analysis in this final rule but refers interested readers to the NPRM's discussion. *See* 80 FR 10974 (Feb. 27, 2015). FRA did not receive any comments in response to this section.

Paragraph (a)(3) in the NPRM proposed requiring an RRP plan's system description to identify all persons that utilize or perform significant safety-related services on the railroad's behalf (including entities such as host railroads, contract operations, shared track/corridor operators, or other contractors). FRA modified paragraph (a)(3) to clarify its requirements and refers readers to the explanation of those changes in the section-by-section analysis for § 271.101(d). FRA does not intend these changes to affect the substance of the rule.

FRA is also adding a paragraph (a)(4) to this section that contains language from § 271.203(b)(4) in the NPRM, which proposed requiring an RRP plan to include a purpose and scope statement describing how any person that utilizes or provides significant safety-related services to a railroad (including host railroads, contract operators, shared track/corridor operators, or other contractors) will support and participate in the railroad's RRP. Because this section requires a railroad's RRP plan to identify such persons as part of its system description, FRA concluded the requirement to describe how such persons will support and participate in the railroad's RRP fits better in this section. FRA's changes are for clarity only. Paragraph (a)(4) requires an RRP plan's system description to describe how the railroad will ensure any person identified under paragraph (a)(3) of this section will support and participate in the railroad's RRP. As an example, paragraph (a)(4) states the system description must describe the extent to which such persons will, as part of the railroad's RRP, help identify hazards, develop and implement mitigation strategies, conduct internal annual assessments, or otherwise perform actions this part requires.

Section 271.207—Consultation Requirements

Section 271.207 implements section 20156(g)(1), which states a railroad required to establish an RRP must consult with, employ good faith, and use its best efforts to reach agreement with, all its directly affected employees, including any non-profit employee labor organization representing a class or craft of directly affected employees of the railroad carrier, on the contents of the RRP plan. This section also implements section 20156(g)(2), which further provides that if a railroad carrier and its directly affected employees, including any nonprofit employee labor organization representing a class or craft of directly affected employees of the railroad carrier, cannot reach consensus on the proposed contents of the RRP plan, then directly affected employees and such organizations may file a statement explaining their views on the plan on which consensus was not reached. *See* 49 U.S.C. 20156(g)(2). The RSIA requires FRA to consider these views during review and approval of a railroad's RRP plan. *Id.*

FRA made several changes to this section from the NPRM. These changes respond to comments received, conform this rule to the SSP final rule, and renumber certain paragraphs for better organization. For clarity, FRA is briefly discussing each provision of this section, even provisions FRA adopts unchanged from the NPRM. To promote consistency with the SSP final rule,

FRA has changed the title of this section from ''consultation process description'' to ''consultation requirements.'' *See* 49 CFR 270.107. This discussion also notes minor differences between the consultation provisions in the RRP and SSP rules.

Paragraph (a)(1) implements section 20156(g)(1) by requiring a railroad to consult with its directly affected employees on the contents of its RRP plan, including any non-profit employee labor organization representing a class or craft of the railroad's directly affected employees. As part of that consultation, a railroad must utilize good faith and best efforts to reach agreement with its directly affected employees on the contents of its plan. FRA has not changed this language from the NPRM.

Paragraph (a)(2) specifies a railroad that consults with a non-profit employee labor organization is considered to have consulted with the directly affected employees that organization represents.

Paragraph (b) states a railroad must have a preliminary meeting with its directly affected employees to discuss how the consultation process will proceed. While the NPRM did not include this language, FRA added it merely as an introductory clause for the subsequent requirements in paragraphs (b)(1) through (4), discussed below, which were all included in proposed paragraphs (a)(3) through (6) of the NPRM. FRA believes including the preliminary meeting requirements in a separate paragraph (b) improves the organization and clarity of this section.

Some commenters to the corresponding consultation provision of the SSP NPRM appeared to believe this preliminary meeting must discuss the substance of the RRP plan. To rectify this misunderstanding, FRA is adding language in paragraph (b) specifying a railroad is not required to discuss the substance of an RRP plan during this preliminary meeting. Rather, the preliminary meeting may be administrative in nature so all parties understand the consultation process and may engage in substantive discussions as soon as possible after the § 271.11 protections become applicable. The preliminary meeting is also an opportunity for the railroad to educate directly affected employees on risk reduction and how it may affect them. The SSP final rule incorporates substantively identical language. *See* 81 FR 53883 and 53900 (Aug. 12, 2016).

Paragraphs (b)(1) through (3) contain the deadlines Class I railroads, ISP railroads, and railroads that STB reclassifies or newly classifies as Class I railroads must meet to hold the preliminary meeting with their directly affected employees. FRA merely renumbered these provisions from paragraphs (a)(3) through (5) of the NPRM to paragraphs (b)(1) through (3) in this final rule. This reorganization does not affect the substance of these paragraphs. FRA refers interested readers to the NPRM discussion of paragraphs (a)(3) through (5) for additional information. *See* 80 FR 10975 (Feb. 27, 2015).

Paragraph (a)(6) of the NPRM, stating a voluntarily-compliant railroad must also consult with its directly affected employees using good faith and best efforts, is in paragraph (b)(4) of the final rule. Paragraph (a)(6) also proposed, however, that because there is no deadline for a voluntarily-compliant railroad to file an RRP plan with FRA, there would also be no requirement for a voluntarily-compliant railroad to meet with its directly affected employees within a certain timeframe. Because FRA decided to include a notification and filing deadline for voluntarily-compliant railroads in § 271.301(b)(4)(i), discussed below, FRA is adding language in paragraph (b)(4) that applies to voluntarily-compliant railroads the same consultation deadlines for ISP railroads and railroads that STB reclassifies or newly classifies as Class I railroads.

Labor Organizations I commented that this section requires railroad management and labor to have only one, non-substantive administrative meeting. To correct any implication that this is the only meeting a railroad must hold to comply with all the consultation process requirements of this section, FRA added language to paragraph (b)(5) clarifying the mandatory preliminary meeting does not constitute full compliance with the consultation process requirements of this section. Although the NPRM did not include this language, it does not impose any additional substantive requirement. The SSP rule does not contain this provision because a similar comment was not received in response to the SSP NPRM. FRA does not intend this to indicate a substantive difference between the consultation requirements of the SSP and RRP rules.

Paragraph (a)(7) of the NPRM, which directed readers to appendix B for additional guidance on how a railroad can comply with the consultation process requirements of this section, is paragraph (c) of the final rule. FRA renumbered this paragraph for better organization and clarity and changed it to direct readers to appendix A instead of appendix B (for reasons discussed in the section-by-section analysis for appendices A and B). FRA discusses appendix A later in this preamble.

Paragraph (d) of the final rule, requiring a railroad to submit, together with its RRP plan, a consultation statement, was paragraph (b) in the NPRM. The consultation statement must contain specific information described in paragraphs (d)(1) through (3) of this final rule, which were renumbered from paragraphs (b)(1), (2), and (4) in the NPRM. Paragraph (d)(1), which requires a consultation statement to describe the process a railroad uses to consult with its directly affected employees, is unchanged from paragraph (b)(1) of the NPRM.

If the railroad cannot reach agreement with its directly affected employees on the contents of its RRP plan, paragraph (d)(2) requires the consultation statement to identify any areas of non-agreement and provide the railroad's explanation for why it believed agreement was not reached. FRA made a minor editorial change to paragraph (d)(2) to be consistent with the SSP final rule by changing the phrase ''was not able to'' to ''could not.'' *See* 81 FR 53901 (Aug. 12, 2016). This change does not affect the substance of this provision. Additionally, while the NPRM used the term ''disagreement,'' FRA changed this to ''non-agreement'' in the final rule to conform more closely with the statutory language in section 20156(g)(1). Although the SSP rule uses ''disagreement'' instead of ''non-agreement,'' FRA does not intend this to indicate a substantive difference between the consultation requirements of the SSP and RRP rules.

Paragraph (b)(3) of the NPRM proposed that if the RRP plan would affect a provision of a collective bargaining agreement between the railroad and a non-profit employee labor organization, the consultation statement must identify that provision and explain how the railroad's RRP plan would affect it. In response to the NPRM, AAR/ASLRRA commented this provision went too far because collective bargaining is a matter between railroads and their employees beyond FRA's jurisdiction. FRA agrees and is not including this provision in the final rule.

Under paragraph (d)(3) of the final rule, proposed as paragraph (b)(4) of the NPRM, the consultation statement must include a service list of the names and contact information for the international/national president of any non-profit employee labor organization representing directly affected employees and any directly affected employee not represented by a non-profit employee labor organization who significantly

participated in the consultation process. FRA did not make any substantive changes to this provision but FRA made the following editorial changes to promote consistency with the SSP final rule and to improve clarity. Although the first sentence in the NPRM addressed both international/national presidents of any non-profit employee labor organization and individual directly affected employees, FRA separated this requirement into two separate sentences and made additional changes to clarify a railroad must include only a directly affected employee who significantly participated in the consultation process on the service list if that employee participated independent of a non-profit employee labor organization. FRA also modified the second to the last sentence of paragraph (d)(3) to add a reference to the plan submission requirements of § 271.301 and to clarify that a railroad must simultaneously provide its RRP plan and consultation statement to individuals the service list identifies. These changes do not affect the substance of this paragraph.[25]

Under paragraph (e)(1) of the final rule, proposed as paragraph (c)(1) in the NPRM, if a railroad and its directly affected employees cannot reach agreement on the proposed contents of an RRP plan, then a directly affected employee may file a statement with the FRA Associate Administrator for Railroad Safety and Chief Safety Officer explaining his or her views on the plan on which agreement was not reached. *See* 49 U.S.C. 20156(g)(2). Except for correcting a typo in the proposed rule (replacing ''then directly affected employees'' with ''the directly affected employees'') and specifically identifying the address for the FRA Associate Administrator for Railroad Safety and Chief Safety Officer, FRA has not changed this paragraph from the NPRM. The above changes do not affect the substance of this paragraph.

Paragraph (e)(2) of the final rule, proposed as paragraph (c)(2) in the NPRM, specifies that a railroad's directly affected employees have 30 days following the railroad's submission of its proposed RRP plan to submit the statement described in paragraph (e)(1) of this section. While the NPRM proposed giving directly affected employees 60 days to submit their statement, FRA believes that 30 days is more appropriate. This decision takes into account that paragraph (b)(3) ensures directly affected employees are provided the RRP plan and the consultation statement at the same time the railroad provides these documents to FRA for review. Moreover, under § 271.301(d) of the final rule (discussed below), FRA will review an RRP plan within 90 days of receipt. As a result, if the directly affected employees had 60 days to submit a statement when agreement on the RRP plan was not reached, FRA would have only 30 days to consider the directly affected employees' view while reviewing the RRP plan. Thirty days would not be enough time to ensure that FRA sufficiently considered the directly affected employees' views during the RRP review process. Finally, the deadline is identical to the deadline for directly affected employee statements in § 271.107(c)(2), which was also changed from a proposed 60-day deadline in the SSP NPRM. *See* 81 FR 53886 (Aug. 12, 2016). To further promote consistency with the SSP final rule, FRA has also removed a reference in proposed paragraph (c)(2) to § 271.301(a)(4). *See* 49 CFR 271.107(c)(2).

In the preamble to the NPRM, FRA explained that it would help a railroad develop its RRP. The preamble to the SSP NPRM expressed a similar intent. Labor Organizations I commented expressing concern that this preamble language indicates that FRA will work exclusively with the railroads, precluding the involvement of any other interested party. Labor Organizations I fear that this would substitute FRA for the directly affected employees in the statutorily-mandated consultation role.

This was not FRA's intent in the preamble discussion. Rather, FRA meant to communicate that FRA would be available to provide guidance to the railroads on the various aspects of the rule, not that there would be an exclusive partnership between FRA and the railroads to develop RRPs. FRA guidance to railroads will not replace Labor Organizations I or any directly affected employee in the consultation role. Under the consultation process required by § 271.207, a railroad must use good faith and best efforts to reach agreement with directly affected employees on the railroad's RRP plan. While the section-by-section analysis discusses ''good faith'' and ''best efforts'' further, a railroad will not be able to meet these standards merely by submitting the required consultation statement. Directly affected railroad employees will therefore always have an opportunity to provide input on the railroad's RRP plan, regardless of guidance FRA provides the railroad on developing an RRP plan.

Labor Organizations I also argue that FRA improperly classified the process under section 20156(g) as one of consultation. Rather, Labor Organizations I believe that section 20156(g) requires a railroad to negotiate or bargain with directly affected employees in accordance with the legal authority of the Railway Labor Act, as amended.

FRA disagrees. Nothing in section 20156(g) requires a railroad to negotiate or bargain with directly affected employees on the contents of an RRP plan. Rather, section 20156(g) requires a railroad to ''consult with, employ good faith and use [its] best efforts to reach agreement with'' directly affected employees (including Labor Organizations I). Throughout SSP and RRP RSAC meetings, FRA referred to this process as one of consultation, not negotiation or bargaining. The NPRM proposed text contained language identical to language in section 20156(g), and FRA does not believe that this language requires a process of negotiation or bargaining consistent with the Railway Labor Act. Requiring a process of negotiation or bargaining would therefore be beyond the scope of FRA's authority in section 20156(g).

Labor Organizations I also expressed concern that various estimates regarding employee involvement and the consultation process in the Regulatory Impact Analysis and the Paperwork Reduction Act analysis were too low. Labor Organizations I claim the estimated time periods were too short and would result in an inconsequential amount of time for consultation on the contents of the plan. FRA notes that the time periods in the analyses were only estimates and that the analyses requested comment on these estimates. *See* 80 FR 10988 and Regulatory Impact Analysis, at ii (Feb. 27, 2015). While Labor Organizations I did not provide suggested estimates that they believe are more appropriate, FRA has changed the final rule to add § 271.113 (discussed above), which requires a railroad to involve its directly affected employees in the establishment and implementation of an RRP. FRA has also updated its estimates of the time RRP safety outreach is expected to take, required under § 271.107 of the final

[25] FRA notes that paragraph (d)(3) in the RRP final rule contains two provisions not in the SSP rule. The first provision states that if an international/national president did not participate in the consultation process, the service list must include information for the designated representative who participated on his or her behalf, and the second states that a railroad may send documents to individuals on the service list via electronic means or other service means reasonably calculated to succeed. The RRP NPRM proposed these provisions (*see* 80 FR 10994 (Feb. 27, 2015)), and their non-inclusion in the SSP final rule was an oversight.

rule, from 15 minutes to 60 minutes per employee.[26]

Labor Organizations I also expressed concern that the NPRM did not contain a penalty schedule or otherwise propose a mechanism for enforcing the consultation process requirements. Labor Organizations I specifically suggested that the DOT Secretary and the President of the United States ''publish an Executive Order supplementing enforcement of [section] 103 by providing for suspension and cancellation of federal payments and benefits to contracting railroads similar to Sec. 7 of E.O. 13,496, . . . codified at 29 CFR [ ] 471.14.''

Regarding the lack of a penalty schedule, FRA typically does not include penalty schedules in an NPRM. Section 271.9(a) of this final rule, however, refers readers to FRA's website for a penalty schedule. Because a penalty schedule is a statement of agency policy, FRA was not required to provide notice and comment before its issuance. *See* 5 U.S.C. 553(b)(3)(A). FRA also notes that none of its enforcement authority is supplemented by a Presidential executive order. FRA concludes, therefore, that an executive order is not necessary to enforce the RRP requirements, even assuming that the President concluded that such an executive order would be legal and appropriate.

Section 271.209—Consultation on Amendments

This section describes the consultation process requirements for amendments to a railroad's RRP plan. Except for replacing an incorrect reference to ''system safety program'' with the correct ''RRP plan'' and replacing the incorrect term ''paragraph'' with ''section,'' FRA adopts this section unchanged from the NPRM. FRA is therefore not repeating the NPRM's section-by-section analysis in this final rule, but refers interested readers to the NPRM's discussion. *See* 80 FR 10976 (Feb. 27, 2015). FRA did not receive any comments on this section.

Section 271.211—Risk-Based Hazard Management Program Process

This section requires an RRP plan to describe the railroad's process for conducting a risk-based HMP. Because FRA received no comments and adopts this section unchanged from the NPRM (except for editorial changes in paragraph (c) to standardize its approach with paragraph (b) and to clarify that the section's requirements are minimal requirements), FRA is not repeating the NPRM's section-by-section analysis in this final rule, but refers interested readers to the NPRM's discussion. *See* 80 FR 10976 (Feb. 27, 2015).

Section 271.213—Safety Performance Evaluation Process

This section requires an RRP plan to describe the railroad's processes for identifying and analyzing its safety culture under § 271.105, monitoring safety performance under § 271.105(b), and conducting safety assessments under § 271.105(c). While this section proposed requiring an RRP plan to describe a railroad's processes for ''measuring'' safety culture in the NPRM, FRA replaced the term ''measuring'' with the phrase ''identifying and analyzing'' for reasons discussed in the above section-by-section analysis for § 271.105. FRA otherwise adopts this section unchanged from the NPRM. *See* 80 FR 10976 (Feb. 27, 2015).

Section 271.215—Safety Outreach Process

This section requires an RRP plan to describe a railroad's processes for communicating safety information to railroad personnel and management under § 271.107. FRA received no comments and adopts this section unchanged from the NPRM, except for exchanging the word ''process'' with ''processes.'' FRA is therefore not repeating the NPRM's section-by-section analysis in this final rule, but refers interested readers to the NPRM's discussion. *See* 80 FR 10976 (Feb. 27, 2015).

Section 271.217—Technology Implementation Plan Process

This section requires an RRP plan to describe a railroad's processes for conducting a technology analysis pursuant to § 271.109(b) and for developing a technology implementation plan pursuant to § 271.109(c). FRA received no comments and adopts this section unchanged from the NPRM. FRA is therefore not repeating the NPRM's section-by-section analysis in this final rule, but refers interested readers to the NPRM's discussion. *See* 80 FR 10976 (Feb. 27, 2015).

Section 271.219—Implementation and Support Training Plan

This section requires an RRP plan to contain a training plan describing the railroad's processes for training, under § 271.111, employees with significant responsibility for implementing and supporting the RRP. Paragraph (a) in the NPRM specified these employees must include persons a railroad identifies under § 271.205(a)(3) as utilizing or performing significant safety-related services on the railroad's behalf. For reasons explained in the section-by-section analysis for § 271.101(d) above, FRA clarified the requirements of this provision. The modified language states that the employees must include employees that a railroad identifies under § 271.205(a)(3) as performing on the railroad's behalf significant safety-related services or utilizing safety-related services provided by the railroad for railroad operations purposes. FRA has not otherwise changed paragraph (a) of this section.

Paragraph (b) in the NPRM proposed requiring the training plan to describe the content and frequency of the RRP training for each position or job function a railroad identifies under § 271.223(b)(3) as having significant responsibilities for implementing the RRP. FRA modified the proposed language in two ways. First, FRA changed the § 271.223(b)(3) reference to § 271.225(b)(3) due to FRA's inclusion of a new § 271.221 in the final rule, discussed below, which resulted in the renumbering of subsequent sections in subpart C of the final rule. AAR/ASLRRA also commented there was some inconsistency in the NPRM because it discusses the training requirement as a one-time event, but also mentions training frequency. FRA has addressed this inconsistency by not including the term ''frequency'' in this section, unlike the proposed language. AAR/ASLRRA are correct that the term is not necessary because the training is a one-time event. FRA has not otherwise changed paragraph (b) of this section.

Section 271.221—Involvement of Railroad Employees Process

This section requires an RRP plan to describe the railroad's processes for involving railroad employees in the establishment and implementation of an RRP under § 271.113. For reasons discussed in the section-by-section analysis for § 271.113 above, FRA did not specifically propose this requirement in the NPRM, but is including it in the final rule to clarify a railroad must involve its employees in the RRP.

This section in the NPRM contained RRP plan requirements for a railroad's internal assessment process in the NPRM. To accommodate this RRP plan involvement requirement, FRA moved the internal assessment process

[26] For additional discussion, see Section 4.1., Consultation: Time Needed to Consult (Economic Impact) and Timeline, of the Regulatory Impact Analysis accompanying this final rule.

requirements to § 271.223 and renumbered the rest of subpart C accordingly.

Section 271.223—Internal Assessment Process

Paragraph (a) of this section, proposed as § 271.221 in the NPRM, requires an RRP plan to describe a railroad's processes for conducting an internal assessment of its RRP under proposed subpart E. Paragraph (b) is reserved. FRA did not receive any comments on this section and, except for moving it to this section in the final rule, adopts this section unchanged from the NPRM. FRA is therefore not repeating the NPRM's section-by-section analysis in this final rule, but refers interested readers to the NPRM's discussion. *See* 80 FR 10976–10977 (Feb. 27, 2015).

Section 271.225—RRP Implementation Plan

Paragraph (a) of this section, proposed as § 271.223 in the NPRM, requires an RRP plan to describe how the railroad will implement its RRP. Except for editorial changes in paragraph (a) and (b)(3), discussed below, FRA adopts this section unchanged from the NPRM. These changes do not affect the substance of this section and FRA did not receive any comments on this section. FRA is therefore not repeating the NPRM's entire section-by-section analysis in this final rule, but refers interested readers to the NPRM's discussion. *See* 80 FR 10977 (Feb. 27, 2015).

FRA modified paragraph (a) to change language in the second sentence from passive to active voice, clarifying that the railroad must fully implement the entire RRP within 36 months of FRA's approval of the plan.

For reasons explained in the section-by-section analysis for § 271.101(d), above, FRA modified the language of paragraph (b)(3) to clarify its requirements. Paragraph (b)(3) requires a railroad's implementation plan to describe the roles and responsibilities of each position or job function with significant responsibility for implementing the railroad's RRP. Paragraph (b)(3) that this includes positions held by contractors that either perform significant safety-related services on the railroad's behalf or utilize significant safety-related services the railroad provides.

Subpart D—Review, Approval, and Retention of Risk Reduction Program Plans

The RSIA requires a railroad to submit its RRP, including any of the required plans, to the FRA Administrator (as delegate of the Secretary) for review and approval. *See* 49 U.S.C. 20156(a)(1)(B). Subpart D, Review, Approval, and Retention of System Safety Program Plans, contains requirements addressing this mandate.

Section 271.301—Filing and Approval

This section contains requirements for the filing of an RRP plan and FRA's approval process. While FRA did not receive any comments on this section, FRA modified this section from the NPRM as discussed below. For background discussion on provisions that FRA has not changed, FRA refers readers to the NPRM's discussion. *See* 80 FR 10977–10978 (Feb. 27, 2015).

Paragraph (a) generally requires a railroad to submit a copy of its RRP plan to the FRA Associate Administrator for Railroad Safety and Chief Safety Officer. Paragraph (a) of the NPRM also contained the RRP plan submission deadlines for Class I railroads, railroads with inadequate safety performance, railroads that the STB classifies or newly classifies as a Class I railroad, and voluntarily compliant railroads. For organizational clarity, FRA moved these deadlines to paragraph (b) and made each deadline separate paragraphs (b)(1) through (4). FRA is further modifying the deadline for ISP railroads in paragraph (b)(2). While the NPRM proposed requiring an ISP railroad to provide FRA an RRP plan no later than 90 days after receiving final notification from FRA under § 271.13, FRA is extending this timeline to 180 days in the final rule to account for the petition process FRA is including in § 271.13(f). Paragraphs (a)(1) through (4) of the NPRM also contained certain requirements for the RRP plan, which FRA moved to paragraph (c) in the final rule. These organizational changes resulted in the renumbering of the other paragraphs in this section but do not affect the substance of the rule.

While the NPRM proposed that a voluntarily-compliant railroad could submit an RRP plan to FRA for review and approval at any time, FRA concluded the proposed approach is vague. FRA based its conclusion on the fact that it leaves uncertainty about when a voluntarily-compliant railroad begins to compile and collect information solely for RRP purposes such that the rule's information protection provisions would apply. Paragraph (b)(4)(i) of the final rule therefore states a voluntarily-compliant railroad must provide FRA written notice of its intent to submit an RRP plan for FRA's review and approval. Under paragraph (b)(4)(ii), the date FRA receives the written notice or February 18, 2021, whichever is later, is the date the voluntarily-compliant railroad may begin to compile or collect information solely for the purpose of planning, implementing, or evaluating an RRP under the information protection provisions of § 271.11. To ensure a voluntarily-compliant railroad does indeed submit an RRP plan for FRA's review and approval once the railroad begins compiling or collecting information solely for RRP purposes, paragraph (b)(4)(iii) states a voluntarily-compliant railroad must submit its RRP plan for review and approval no later than 180 days after FRA receives the railroad's written notice. This is the same amount of time an ISP railroad has to submit its RRP plan under paragraph (b)(2).

Paragraphs (c)(1) through (4), proposed as paragraphs (a)(1) through (4) of the NPRM, require a railroad to provide certain additional information as part of its submission. Aside from the reorganization, FRA did not make any changes to the language in paragraphs (c)(1) and (2). For reasons explained by the section-by-section analysis for § 271.101(d), above, FRA changed paragraph (c)(3) to clarify its requirements. Paragraph (c)(3) requires a railroad's RRP plan to include the contact information for the senior representatives of any person that has entered into a contractual relationship with the railroad to either perform significant safety-related services on the railroad's behalf or to utilize significant safety-related services the railroad provides for railroad operations. This includes the senior representatives of host railroads, contract operators, shared track/corridor operators, and other contractors. This change does not affect the substance of this provision.

Paragraph (c)(4), proposed as paragraph (a)(4) in the NPRM, requires a railroad to submit a statement describing how it consulted with its directly affected employees on the contents of its RRP plan under § 271.207(d). This paragraph also reminds directly affected employees that they have 30 days following the railroad's submission of its proposed RRP plan to file a statement under § 271.207(e)(2). FRA has made three changes to these requirements from the NPRM. First, this paragraph referenced § 271.207(b) and (c) in the NPRM, and FRA changed these references to § 271.207(d) and (e)(2) to reflect organizational changes to § 271.207. For plain language purposes, FRA also changed the phrase ''in accordance with'' to ''under.'' These changes do not affect the substance of this requirement. Finally, while the NPRM proposed

providing directly affected employees 60 days to submit a statement following a railroad's submission of its RRP plan, FRA believes 30 days is more appropriate. The section-by-section analysis for § 271.207(e)(2) explains why FRA has made this change.

Paragraph (d), proposed as paragraph (b) in the NPRM, explains how FRA will approve a railroad's RRP plan. Except for updating references to reflect organizational changes in § 271.207, making a non-substantive editorial change in paragraph (d)(1), extending a deadline in paragraph (d)(3), and adding minor provisions in paragraphs (d)(3) and (4), FRA adopts this paragraph unchanged from the NPRM. In paragraph (d)(1), FRA changed the language ''prior to the commencement of railroad operations'' to ''before the start of railroad operations'' for plain language purposes. Under paragraph (d)(3), when a railroad receives notification that FRA has not approved its plan and notice of the specific points in which the plan is deficient, the railroad has 90 days to correct all of the deficiencies identified and resubmit the plan to FRA. Both the SSP NPRM and the RRP NPRM proposed giving a railroad 60 days to correct identified deficiencies, but FRA received comments in response to the SSP NPRM expressing concern that 60 days was not a sufficient amount of time for a railroad to address the deficient points of an SSP plan. *See* 81 FR 53888 (Aug. 12, 2016) and 80 FR 10995 (Feb. 27, 2015). The SSP final rule addressed this concern by extending the deadline to 90 days, and this final rule does the same to keep the rules consistent. *See* 49 CFR 270.201(b)(3) and 81 FR 53888 (Aug. 12, 2016). FRA has also modified paragraph (d)(3) to include language indicating that FRA will review a corrected RRP plan within 60 days of receipt.

FRA has modified paragraph (d)(4) to include language stating FRA's approval of a railroad's RRP plan does not constitute approval of the specific actions the railroad will implement under its RRP plan and shall not be construed as establishing a Federal standard regarding those specific actions. Section V.A.5 of the preamble, above, explains that FRA has added this language to specifically preserve State claims.

Paragraph (e), proposed as paragraph (c) in the NPRM, specifies that all documents required to be submitted to FRA under this part may be submitted electronically under the procedures in appendix B to this part. Other than the reorganization and directing readers to appendix B instead of appendix C, as proposed in the NPRM (for reasons discussed in the section-by-section analysis for appendix B), FRA adopts this provision unchanged from the NPRM.

Section 271.303—Amendments

This section addresses the process a railroad must follow whenever it amends its FRA-approved RRP plan, regardless of whether the amendments are substantive or non-substantive. Except for additional language FRA added to paragraph (a) and clarifying changes in paragraphs (b) and (c), discussed below, FRA adopts this section unchanged from the NPRM. FRA also did not receive any comments on this section. For discussion on provisions FRA has not changed, FRA refers interested readers to the NPRM's discussion. *See* 80 FR 10978 (Feb. 27, 2015).

Paragraph (a) in the NPRM stated that for substantive amendments, a railroad must follow the process in its RRP plan under § 271.209 for consulting with its directly affected employees. In the final rule, FRA renumbered this provision paragraph (a)(1) and added language clarifying that a railroad must also submit a consultation statement to FRA. FRA also added language in paragraph (a)(2) specifying that if a railroad and its directly affected employees cannot reach agreement on the proposed contents of a substantive amendment, the directly affected employees may file a statement with FRA under § 271.207(e)(1) procedures. Paragraph (a)(2) gives directly affected employees 15 days following the railroad's submission of the proposed amendment to submit a statement. Fifteen days is sufficient time for the statement because issues associated with amending an RRP plan are likely to be less complex than issues associated with initially developing a new RRP plan. FRA is including this provision because FRA believes a railroad substantively amending its RRP plan must follow all the consultation process requirements that apply when a railroad is initially developing a plan. A railroad cannot either evade consultation process requirements or deprive directly affected employees of the opportunity to submit a statement to FRA by substantively amending an RRP plan FRA already approved. This paragraph does not apply to non-substantive amendments (*e.g.,* amendments updating names and addresses of railroad personnel). If a railroad is uncertain whether a proposed amendment is substantive or non-substantive, it should contact FRA for guidance.

Paragraph (b) contains requirements for filing an RRP plan amendment. The only change FRA made to this paragraph was to replace ''prior to'' with ''before'' for plain language purposes.

Paragraph (c) describes how FRA will review and approve a railroad's proposed amendment. Paragraph (c)(1) in the NPRM stated that FRA will review an amendment within 45 days of receipt and then notify the primary contact person of the railroad whether FRA approves the proposed amendment. FRA made non-substantive editorial changes to this provision to improve clarity and change passive voice to active voice. FRA also added language in paragraphs (c)(1) and (2) clarifying that FRA will also provide this notification to each individual identified in the service list accompanying the consultation statement under § 271.303(a)(1). Once again, FRA added this language to ensure the process for approving substantive amendments is the same as the process for initially approving a railroad's RRP plan. FRA adopts paragraph (c)(3) unchanged from the NPRM. *See* 80 FR 10978 (Feb. 27, 2015).

Section 271.305—Reopened Review

This section provides that, for cause stated, FRA may reopen review of an RRP plan or amendment (in whole or in part) after approval of the plan or amendment. While this section of the NPRM stated that FRA may ''reopen consideration'' of an RRP plan or amendment, FRA has replaced this phrase with ''reopen review'' because ''review'' is the term used in the section title and elsewhere in the final rule to describe FRA's role in approving an RRP plan. The determination of whether to reopen review is solely within FRA's discretion on a case-by-case basis. As an example, the NPRM explained that FRA could reopen review if it determines the railroad has not been complying with its plan/amendment or if FRA obtains information that was not available when FRA originally approved the plan or amendment.

In response to this section in the NPRM, AAR/ASLRRA commented the phrase ''for cause stated'' was unlimited and this section was unacceptably vague. FRA does not believe this provision needs additional specificity. FRA further notes that reopening an RRP plan for review does not necessarily mean the plan does not comply with the final rule. FRA will work with a railroad and its directly affected employees if it reopens review to ensure the railroad and employees understand and can address FRA's cause stated.

Section 271.307—Retention of RRP Plans

This section contains requirements for railroads to retain their RRP plans. Except for adding language in paragraph (b) clarifying that a railroad must also make a copy of any subsequent amendment to an RRP plan available for inspection and copying (in addition to the plan itself), FRA adopts this section unchanged from the NPRM. FRA also did not receive any comments on this section so it is therefore not repeating the NPRM's section-by-section analysis, but refers interested readers to the NPRM's discussion. *See* 80 FR 10978 (Feb. 27, 2015).

Subpart E—Internal Assessments

To help ensure an RRP is properly implemented and effective, a railroad must evaluate its program annually. Subpart E contains the railroad requirements to conduct an internal assessment of its RRP. FRA did not receive any comments on this subpart. Except for updating references in the NPRM to reflect organizational changes in the final rule [27] and the minor changes discussed below for §§ 271.403 and 271.405, FRA adopts this subpart unchanged from the NPRM. FRA is therefore not repeating the NPRM's section-by-section analysis in this final rule, but refers interested readers to the NPRM's discussion. *See* 80 FR 10978–10979 (Feb. 27, 2015).

Section 271.403—Internal Assessment Improvement Plans

Paragraph (b)(2) in this section of the NPRM stated that a railroad's improvement plan must describe recommended improvements, ''including any necessary revisions or updates to the RRP plan which would be made through the amendment process. . . .'' FRA believes the term ''necessary'' is vague, and therefore changed this language in the final rule to read, ''including any proposed revisions or updates to the RRP plan the railroad expects to make through the amendment process . . . .'' The changed language also clarifies that these are amendments the railroad expects to make. FRA does not intend these changes to change the substance of this paragraph.

Section 271.405—Internal Assessment Reports

FRA has made changes to paragraph (b)(3) of this section to conform its language with the changes FRA has made to § 271.403(b)(2), discussed above.

Subpart F—External Audits

This subpart explains FRA's process for conducting audits of the railroad's RRP and establishes requirements for the actions a railroad must take in response to FRA's audits. FRA's audits will focus on reviewing the railroad's RRP process and ensuring that the railroad is following the processes and procedures described in its FRA-approved RRP plan. FRA did not receive any comments on this subpart and except for a modification to § 271.501 discussed below, adopts it unchanged from the NPRM. FRA is therefore not repeating the NPRM's section-by-section analysis in this final rule, but refers interested readers to the NPRM's discussion. *See* 80 FR 10979 (Feb. 27, 2015).

Section 271.501—External Audits

This section in the NPRM generally stated FRA would cause external audits to be conducted. FRA has modified this section to clarify that a railroad must make documentation kept pursuant to its RRP plan available to FRA or State railroad safety inspectors for copying and inspection.

Appendix A to Part 271—Federal Railroad Administration Guidance on the Risk Reduction Program Consultation Process

As proposed in the NPRM, FRA intended appendix A to contain a schedule of civil penalties for use in connection with this final rule. However, FRA has decided to provide such a schedule on its website instead of as an appendix to the final rule. Please see the discussion of § 271.9, Penalties and responsibility for compliance, in the section-by-section analysis for further details.

FRA is therefore moving appendix B, as proposed in the NPRM, to appendix A in the final rule. Appendix A contains guidance on complying with § 271.207, which states that a railroad must in good faith consult with, and use its best efforts to reach agreement with, all of its directly affected employees on the contents of the RRP plan. The appendix begins with a general discussion of the terms ''good faith'' and ''best efforts,'' explaining they are separate terms and each has a specific and distinct meaning. For example, the good faith obligation is concerned with a railroad's state of mind during the consultation process, and the best efforts obligation is concerned with the specific efforts a railroad makes to try to reach agreement with its directly affected employees. The appendix also explains that FRA will determine a railroad's compliance with the § 271.207 requirements on a case-by-case basis and explains that FRA may disapprove a plan if a railroad fails to consult with its directly affected employees in good faith and use best efforts.

Further, the appendix contains specific guidance on the process a railroad may use to consult with its directly affected employees. This guidance does not establish prescriptive requirements a railroad must comply with, but provides a road map as an example of how a railroad may conduct the consultation process. The guidance also distinguishes between employees who are represented by a non-profit employee labor organization and employees who are not, as the processes a railroad may use to consult with represented and non-represented employees could differ significantly. Overall, however, the appendix stresses there are many ways a railroad may choose to consult with its directly affected employees to comply with the rule. Therefore, it is important to maintain a flexible approach to the § 271.207 consultation process requirements, so a railroad and its directly affected employees may consult in the manner best suited to their specific circumstances.

Appendix B to Part 271—Procedures for Submission of RRP Plans and Statements From Directly Affected Employees

Appendix B in the NPRM proposed guidance on complying with the consultation process requirements, and has been moved to appendix A in the final rule for reasons discussed above. FRA is therefore moving appendix C, as proposed in the NPRM, to appendix B in the final rule. Appendix B provides railroads and directly affected employees the option to file RRP plans or consultation statements electronically. The NPRM requested comment regarding whether FRA should allow electronic submission of RRP materials. FRA did not receive any comments against electronic submission and, therefore, is including this appendix unchanged in the final rule.

FRA will create a secure document submission site and will need basic information from railroads or directly affected employees before setting up a user's account. To provide secure access, FRA will also need information on the railroad's points of contact. FRA anticipates it will be able to approve or disapprove all or part of a program and generate automated notifications by

[27] To reflect organizational changes in the final rule, FRA changed a reference in § 271.401(a) from § 271.301(b) to § 271.301(d) and a reference in § 271.401(b)(1) from § 271.223(b) to § 271.225(b).

email to a railroad's points of contact. Thus, each point of contact must understand that by providing any email addresses, the railroad is consenting to receive approval and disapproval notices from FRA by email. Railroads that allow notice from FRA by email benefit from receiving such notices quickly and efficiently.

Railroads that choose to submit printed materials to FRA must deliver them directly to the specified address. Some railroads may choose to deliver a CD, DVD, or other electronic storage format to FRA rather than requesting access to upload the documents directly to the secure electronic database. Although that is an acceptable method of submission, FRA encourages each railroad to utilize the electronic submission capabilities of the system. If FRA cannot read the type of electronic storage format sent, FRA will reject the submission.

VII. Regulatory Impact and Notices

A. Executive Orders 12866 and 13771, Congressional Review Act, and DOT Regulatory Policies and Procedures

This rule is a significant regulatory action within the meaning of Executive Order 12866 (E.O. 12866) and DOT policies and procedures. *See* 44 FR 11034 (Feb. 26, 1979). FRA made this determination by finding that, although the economic effects of this regulatory action would not exceed the $100 million annual threshold defined by E.O. 12866, the rule is significant because of the substantial public interest in transportation safety. 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). Additionally, this final rule is considered an E.O. 13771 regulatory action. Details on the estimated costs of this final rule can be found in the rule's RIA, which FRA has prepared and placed in the docket (docket no. FRA–2009–0038). The RIA details estimated costs the railroads regulated by the rule are likely to incur over a ten-year period.

FRA did not estimate the full incremental costs of railroads conducting additional and systematic hazard and risk analyses or implementing actions to mitigate identified hazards and risks. FRA lacks information to reliably estimate such costs because FRA does not know the specific level of hazards and risks on impacted railroads or the means railroads will use to mitigate these risks. FRA nevertheless expects railroads will implement the most cost-effective mitigations to eliminate or mitigate hazards, and the rule does not require railroads to implement mitigations that would result in net costs. As such, FRA expects that a railroad will only implement mitigation efforts that are net beneficial to the railroad.

The below tables summarize the rule's total costs over a ten-year period based on Class I railroads having a 43-percent pre-compliance rate and ISP railroads having no pre-compliance, with a total cost of $40.2 million, using a 7-percent discount rate (PV), 7-percent) (Table 5) and $51.0 million, using a 3-percent discount rate (PV, 3-percent) (Table 6). The annualized costs are $5.7 million (PV, 7-percent) and $5.9 million (PV, 3-percent).

TABLE 5—SUMMARY OF THE RULE'S TOTAL COSTS (TEN-YEAR PERIOD), ASSUMING 43-PERCENT CLASS I PRE-RULE COMPLIANCE; PV, 7-PERCENT

Costs	Class I railroads	ISP railroads	All railroads
Subpart A: General	.....	$7,000	$7,000
Subpart B: RR Programs	$35,725,000	2,216,000	37,941,000
Subpart C: RRP Plans	656,000	1,053,000	1,709,000
Subpart D: Review and Approval of Plans	2,000	7,000	9,000
Subpart E: Internal Assessments	171,000	312,000	483,000
Subpart F: External Audits	28,000	32,000	60,000
Total Cost	36,582,000	3,627,000	40,209,000
Annualized	5,210,000	516,000	5,726,000

TABLE 6—SUMMARY OF THE RULE'S TOTAL COSTS (TEN-YEAR PERIOD), ASSUMING 43-PERCENT CLASS I PRE-RULE COMPLIANCE; PV, 3-PERCENT

Costs	Class I railroads	ISP railroads	All railroads
Subpart A: General	.....	$9,000	$9,000
Subpart B: RR Programs	$45,156,000	3,011,000	48,167,000
Subpart C: RRP Plans	771,000	1,329,000	2,100,000
Subpart D: Review and Approval of Plans	2,000	8,000	10,000
Subpart E: Internal Assessments	230,000	413,000	643,000
Subpart F: External Audits	37,000	43,000	80,000
Total Cost, 3% present value	46,197,000	4,813,000	51,000,000
Annualized, 3%	5,416,000	564,000	5,979,000

The final rule will require each Class I and ISP railroad to create and implement an RRP. As part of an ongoing process, the final rule will require each railroad and its employees to collaboratively identify, rank, and address safety hazards. FRA concludes that the final rule will result in each affected railroad creating a systematic

approach to safety that achieves benefits from inter-department coordination similar to the type of benefits observed through the FRA-sponsored C³RS program.[28] FRA expects that the final rule will improve the effectiveness of a railroad's hazard mitigation efforts, which will result in the primary benefit of decreasing the frequency of accidents/incidents. Other benefits that will come from promulgating the rule include reduced railroad and non-railroad property damage, railroad and highway travel delays, cleanup costs, employee absenteeism, and emergency response costs, among others. Lastly, FRA expects that the final rule will increase railroad productivity and profitability, due to substantially better employee morale, improved working conditions, and a more effective allocation of hazard safety mitigation resources.

Benefits that come from the final rule will vary from railroad to railroad. These benefits are based on each railroad's organizational structure, the ability for labor and management to collaborate, and the steps the railroad takes to implement hazard analysis and mitigation. FRA could not reliably predict the specific risks that each freight railroad will identify, the actions each freight railroad will take to mitigate such risks, or the success rate of such actions. Details on the estimated benefits of this final rule can be found in the rule's RIA, which FRA has prepared and placed in the docket (docket no. FRA–2009–0038).

FRA expects that the final rule will increase the effectiveness of railroad hazard mitigation strategies, which will reduce the frequency of accidents and incidents on the general railroad system. FRA also expects that the final rule will result in increased employee morale and improved working conditions, which will improve railroad productivity. These benefits will result because the final rule:

1. Ensures that railroads keep their RRP current and in place;
2. Improves safety culture;
3. Requires ongoing employee involvement and proactive collaboration between labor and management; and
4. Provides information protection, which allows for a systematic risk-based hazard analysis.

The final rule requires each Class I railroad to have a fully implemented RRP within five years of the rule's effective date and requires the first set of ISP railroads to implement all portions of their RRPs within six years after the final rule's effective date.[29] FRA anticipates that railroads may implement some components of their RRP plan before the required implementation dates specified in the final rule. Therefore, this analysis estimates that the final rule will start generating benefits in the fourth year (year 2022), when Class I railroads will have substantially implemented their RRPs. As previously discussed, Class I railroads have in place existing activities related to the final rule's required components. The existing levels of pre-rule compliance reduce the size of potential benefits that follow from issuing the final rule.

B. Regulatory Flexibility Act and Executive Order 13272

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) and Executive Order 13272 (67 FR 53461, Aug. 16, 2002) require agency review of proposed and final rules to assess their impacts on small entities. An agency must prepare a Final Regulatory Flexibility Analysis (FRFA) unless it determines and certifies that a rule, if promulgated, would not have a significant economic impact on a substantial number of small entities. FRA is publishing this FRFA to describe the potential impact of the final rule on small businesses.

1. Statement of Need for, and Objectives of, the Rule

FRA is requiring each Class I freight railroad and ISP freight railroad to develop and implement an RRP, a structured program with proactive processes and procedures a railroad develops and implements to identify and eliminate or mitigate hazards and the resulting risks on its system. An RRP works by encouraging a railroad and its employees to proactively collaborate to identify hazards and determine what, if any, action to take to eliminate or mitigate the resulting risks. The rule provides each railroad with a substantial amount of flexibility to establish an RRP based on its specific operations. FRA is issuing the RRP rule as part of its efforts to continuously improve rail safety and to satisfy in part the statutory mandate in sections 103 and 109 of the RSIA.

The rule is intended to focus on increased safety, care, and protection of railroad employees, customers, and the general public. The rule will also help ensure railroads provide a safer workplace environment for their employees. Conformance and compliance with the rule, rather than a voluntary system, will better facilitate and ensure industry-wide efforts, resulting in measurable improvement in the performance and quality of safety management processes.

Even though FRA has issued safety regulations and guidance that address many aspects of railroad operations, there are gaps in safety and hazards. Risks may arise from these gaps. RRPs will provide railroads with the tools to systematically and continuously evaluate their systems to identify the gaps in safety and eliminate or mitigate the hazards and risks that result from these gaps.

The rule responds to the Congressional mandate in section 103 of the RSIA, which provides that FRA, by delegation from the Secretary, shall require each Class I railroad and ISP railroad to establish a railroad safety risk reduction program. *See* 49 U.S.C. 20156(a)(1).[30] The rule also conforms to section 109 of the RSIA, which directs FRA, by delegation from the Secretary, to conduct a study to determine if it is in the public interest to withhold certain information, including a railroad's assessment of its safety risks and its statement of mitigation measures, from discovery and admission into evidence in proceedings for damages involving personal injury and wrongful death. Section 109 authorizes FRA, by delegation from the Secretary, to prescribe a rule, subject to notice and comment, to address the results of the study. *See* 49 U.S.C. 20119.

The RSIA requirements explain the congressionally mandated need for action. Under 49 U.S.C. 20103(a), ''[t]he Secretary of Transportation, as necessary, shall prescribe regulations and issue orders for every area of railroad safety supplementing laws and regulations in effect on October 16, 1970.'' The Secretary's responsibility under this provision and the balance of the railroad safety laws has been delegated to the FRA Administrator under 49 CFR 1.89.

[28] *See* U.S. Department of Transportation, Federal Railroad Administration, ''Continued Improvement at One C3RS Site'', June 2015, *available at https://rosap.ntl.bts.gov/view/dot/12204/dot_12204_DS1.pdf* (Accessed December 10, 2018).

[29] An ISP railroad should begin to realize benefits approximately three years after FRA approves its RRP plan, the point when the final rule requires the ISP railroad to have fully implemented its RRP. The final rule requires each ISP railroad that is part of the first group of ISP railroads to implement in full an RRP by the sixth year.

[30] While the RSIA also directs FRA to require passenger railroads to establish railroad safety risk reduction programs, FRA has published a separate SSP rule that addresses the passenger railroad mandate. *See* 81 FR 53850 (Aug. 12, 2016).

2. Summary of Significant Issues Raised by Public Comments, Summary of Assessment of Such Issues, and Statement of Any Changes in Rule as Result of Such Comments

There is an extensive section, above, discussing comments. This section discusses comments particularly applicable to small railroads.

ISP Determination: ASLRRA expressed concern that FRA's proposed methodology for identifying ISP railroads would select a disproportionate number of the smallest railroads. To assess this concern, FRA conducted several analyses of data from FRA's RAIRS, the system that would provide FRA data for the inadequate safety performance methodology. To approximate the proposed methodology, FRA conducted the analyses for the three-year period from 2012 through 2014, the latest years for which a full 12 months' data were available at the time of the analysis.

The first analysis identified and evaluated all railroads the proposed methodology would analyze for inadequate safety performance (*i.e.,* Class II and III freight railroads that operate on the general system). On average, these railroads reported about 231,000 total train miles operated and 200,000 employee hours between 2012 and 2014.

FRA then used the proposed methodology for identifying ISP railroads to evaluate Class II and III railroads for inadequate safety performance. Railroads determined to have inadequate safety performance reported, on average, 32,000 total train miles operated and 35,000 employee hours between 2012 and 2014. These averages are substantially lower than averages for the entire pool of Class II and III railroads the proposed methodology would evaluate. Based on this result, FRA shares ASLRRA's concern that the proposed methodology would over-select the smallest railroads.

FRA has therefore changed the proposed methodology to include a preliminary selection in the quantitative analysis phase. This preliminary selection will help avoid over-selecting the smallest railroads by utilizing the absolute number (rather than rates) of two factors regarding a railroad's safety performance. FRA has applied this methodology to RAIRS data. On average, railroads identified as having inadequate safety performance reported 146,000 train miles operated and 165,000 employee hours from 2012 through 2014. These averages are much closer to the averages for the entire pool of Class II and III freight railroads that the methodology will initially evaluate.

Appeal of FRA's ISP Determination: AAR/ASLRRA commented urging FRA to establish an appeals process for railroads that the methodology identifies as having inadequate safety performance. FRA agrees including an appeals process for railroads determined to have inadequate safety performance is fair. In the final rule, FRA therefore added a process for railroads to petition the FRA Administrator for reconsideration of inadequate safety performance determinations under existing procedures to appeal to the Administrator (*e.g.,* procedures regarding petitions for waiver of safety rules under 49 CFR part 211, subpart C). These procedures are well-established and should be familiar to the railroad industry.

Information Protection: While small railroad commenters favored information protection, FRA received several comments arguing the proposed information protections are too narrow. ASLRRA commented FRA improperly relied on section 409 and the Supreme Court's decision in *Guillen,* and therefore FRA is not protecting data as Congress intended in the RSIA. ASLRRA also questions FRA's explanation in the NPRM preamble that the information protections would only extend to the Short Line Safety Institute (Institute) if FRA finds the Institute is part of a complete RRP program. *See* 80 FR 10964 (Feb. 27, 2015). As Section V.A.8 explains above, FRA disagrees with these comments and believes it has properly limited the scope of the information protections, the protections are consistent with Congress' intent in the RSIA, and FRA lacks authority under RSIA to extend information protections to programs that do not fully meet the requirements of this RRP final rule.

AAR/ASLRRA also commented on the NPRM preamble statement that § 271.11 would only protect information once FRA approves a railroad's RRP plan. They believe that approach does not make sense and weakens the rule's proposed protections. As Section V.A.8 explains above, FRA agrees with AAR/ASLRRA and does not intend to limit the information protections only to information a railroad compiles or collects for an RRP plan FRA has already approved.

Performance-based rule and flexibility: As Section V.B.2 explains above, the NPRM described RRP as a performance-based rule that would not establish prescriptive requirements that may be appropriate for one railroad but unworkable for another. Several commenters supported FRA's decision to propose a performance-based, flexible RRP rule, and AAR/ASLRRA acknowledged the performance-based nature of RRP. The performance-based nature of the RRP final rule gives a smaller railroad the flexibility to tailor the rule's requirements to its specific operations and amount of resources.

Short Line Safety Institute: As Section V.B.8 explains above, ASLRRA commented that small railroad participation in the Institute should suffice as complete compliance with the requirements in the NPRM. ASLRRA also claims FRA would fulfill the SBREFA requirement to grant special considerations to small businesses by accepting participation in the Institute as satisfying RRP requirements. FRA currently cannot determine, however, whether the Institute will fully comply with the RSIA mandate or the requirements of this final rule. Rather, FRA believes it is more appropriate to make this determination when reviewing RRP plans under § 271.301 of the final rule. FRA also notes that the final rule will not unduly burden short line and regional railroads because of its scalability and flexibility.

3. The Response of the Agency to Any Comments Filed by the Chief Counsel for Advocacy of the Small Business Administration

FRA did not receive any comments from the Chief Counsel for Advocacy of the Small Business Administration.

4. Description and Estimate of Number of Small Entities to Which the Final Rule Applies

''Small entity'' is defined in 5 U.S.C. 601 as a small business concern that is independently owned and operated, and is not dominant in its field of operation. The U.S. Small Business Administration (SBA) has authority to regulate issues related to small businesses, and stipulates in its size standards that a ''small entity'' in the railroad industry is a for profit ''line-haul railroad'' that has fewer than 1,500 employees, a ''short line railroad'' with fewer than 500 employees, or a ''commuter rail system'' with annual receipts of less than 15 million dollars. *See* ''Size Eligibility Provisions and Standards,'' 13 CFR part 121, subpart A. Additionally, 5 U.S.C. 601(5) defines as ''small entities'' governments of cities, counties, towns, townships, villages, school districts, or special districts with populations less than 50,000.

Federal agencies may adopt their own size standards for small entities in consultation with SBA and in conjunction with public comment.

Under that authority, FRA published a final statement of agency policy formally establishing ''small entities'' or ''small businesses'' as railroads, contractors, and hazardous materials shippers that meet the revenue requirements of a Class III railroad under 49 CFR 1201.1–1, which is $20 million or less in inflation-adjusted annual revenues, and commuter railroads or small governmental jurisdictions that serve populations of 50,000 or less. *See* 68 FR 24891 (May 9, 2003) (codified at 49 CFR part 209, appendix C). The $20 million limit is based on the STB's revenue threshold for a Class III railroad carrier. Railroad revenue is adjusted for inflation by applying a revenue deflator formula in accordance with 49 CFR 1201.1–1. FRA is using this definition for the final rule. For other entities, the same dollar limit in revenues governs whether a railroad, contractor, or other respondent is a small entity.

Railroads

In the universe of railroads that potentially have to comply with the final rule, there are 7 Class I railroads, 11 Class II railroads (1 of which is classified as a passenger railroad that will be excepted from the final rule), and 735 Class III freight railroads. Out of the 735 Class III freight railroads, the final rule excepts railroads not on the general system and tourist railroads, leaving approximately 600 Class III railroads as small entities that may be subject to the requirements of the final rule.[31]

To identify Class II and Class III railroads that must comply with the final rule because they demonstrate inadequate safety performance, FRA will annually conduct a two-phase analysis. The first phase is a statistically-based quantitative analysis of fatalities, FRA-reportable injuries/illnesses, FRA-reportable accidents/incidents, and FRA safety violations; and the second phase is a qualitative assessment that includes input from affected railroads and their employees. *See* § 271.13 of the final rule for a full description of FRA's process for determining inadequate safety performance.

Because FRA's initial inadequate safety performance analysis will occur at least one year after the RRP final rule goes into effect, it is impossible for FRA to know how many Class III railroads will be required to comply. FRA reviewed a 3-year rolling average of safety data to test the selection process. This analysis accounted for the types of information that railroads and employees could present to FRA during the qualitative review process. Such information could serve to refute the quantitative analysis' identification of a railroad as demonstrating inadequate safety performance. Based on this analysis, FRA expects to identify approximately 10 Class II and Class III freight railroads that demonstrate inadequate safety performance in year 2 of the 10-year period of the analysis. In each subsequent year, FRA expects to identify five additional ISP railroads. Therefore, by year 10, FRA will have identified approximately 50 ISP railroads.

FRA expects the number of ISP railroads will reach a maximum of 50 railroads by year 10, at which point the number of ISP railroads should flatten out or decline. In estimating the maximum number of ISP railroads, FRA considered the following factors: (1) Industry-wide safety performance improvement; (2) in year 7 of the analysis, some ISP railroads will seek and receive relief from being in the program after complying for 5 years; (3) the size of the railroad pool being examined for inadequate safety performance would shrink as more railroads are required to comply with part 271; and (4) those railroads not identified as being an ISP railroad will observe the positive behaviors and results of ISP railroads and will embrace the better safety practices without having a formal RRP program.

For purposes of this FRFA, FRA expects that each ISP will be a Class III railroad (small railroad).

Contractors

Some railroads use contractors to perform many different functions on their railroads. For some of these railroads, contractors perform safety-related functions, such as operating trains. For assessing the impact of an RRP, contractors fall into two groups: Larger contractors that perform a primary operating or maintenance function for the railroads, and smaller contractors that perform ancillary functions to the primary operations. Larger contractors are typically employed by sizable private companies or part of an international conglomerate. Smaller contractors may perform such duties as brush clearing or painting facilities.

Safety-related policies, work rules, guidelines, and regulations are imparted to the small contractors today as part of their contractual obligations and qualification to work on the Class I freight railroads, and potentially to work for ISP railroads. FRA sees minimal additional burden to imparting the same type of information under each railroad's RRP. A very small administrative burden may result.

Under the final rule, contractors (small or large) that provide significant safety-related services are expected to have minimal burden under the rule. For example, while the final rule requires the railroad to involve the persons that provide significant safety-related services in the railroad's RRP, it doesn't require the entity to do any training. Thus, any burden imposed on contractors would be indirect or considered in the contract with the pertinent railroad or both.

5. Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule, Including Estimate of Small Entities Regulated by Rule

The rule will require an ISP railroad to develop and implement an RRP under a written RRP plan FRA has reviewed and approved. There are several reporting, recordkeeping, and compliance costs associated with the final rule. FRA believes that the added burden of recordkeeping is marginal due to the final rule requirements.

The total 10-year cost of this final rule is $40.2 million (PV, 7%) and $51.0 million (PV, 3%), of which FRA estimates $3.6 million (PV, 7%) and $4.5 million (PV, 3%) or less will be attributable to small entities. Based on FRA's RIA, which has been placed in the docket, the average Class III ISP railroad will incur an average burden per year. If, for example, ISP railroads comply with the final rule for an average of eight years, then the total cost will be approximately $143,000 (PV, 7%) and $168,000 (PV, 3%) per ISP railroad.

However, due to the small number of small railroads that are estimated to be impacted by this final rule, the cost per railroad could be found to be significant. For a thorough presentation of cost estimates, please refer to the RIA, which has been placed in the docket for this rulemaking.

The following section outlines the potential additional burden on small railroads for each subpart of the final rule.

- Subpart A—General

The policy, purpose, and definitions outlined in subpart A, alone, will not impose a significant burden on small railroads. However, there is the small requirement for notifying employees of

[31] Total number of Class III railroads potentially impacted = 735 Class III railroads − 43 Class III railroads not on the general system − 93 Class III railroads that are tourist railroads = 599 Class III railroads.

the railroad that FRA's quantitative analysis has found that the railroad may demonstrate inadequate safety performance. This subpart of the final rule will impose less than 1 percent of the total burden for small entities.

• Subpart B—Risk Reduction Program Requirements

Subpart B of the final rule will have a proportional effect directly related to the size and complexity of a railroad and will impose approximately 60 percent of the total burden for small entities. Generally, this subpart describes what a railroad must develop and include in its RRP. For example, it requires the development of a risk-based HMP (which includes a risk-based hazard analysis and the design and implementation of mitigation strategies), safety performance evaluation, and technology implementation plans.

Because of the scalable nature of the final rule, the requirements of an RRP will be much less complex for a small railroad than they will be for a Class I railroad. Additionally, several characteristics of small railroads should also limit the number and types of hazards for the RRP to address. These characteristics include the concentrated geography of operation in a small area, the short distance of operation, and a non-fragmented and non-diffused work force (in other words, most employees of a small railroad are in one place). RRP requirements such as technology implementation plans should also not be burdensome. This is because small railroads are very limited in the resources they can allocate for new technologies. FRA expects that small railroads will rely on tried-and-true technologies that have been thoroughly tested elsewhere.

• Subpart C—Risk Reduction Program Plan Requirements

Subpart C of the final rule will have a proportional effect directly related to the size and complexity of a railroad. This subpart of the final rule contains the requirements for RRP plans and will impose approximately 29 percent of the total burden for small entities. For example, it requires a plan statement on each RRP element mandated in subpart B and plan statements related to safety policy and goals, a system description, the consultation process, and an RRP implementation plan. This subpart of the final rule is primarily the paperwork or written plan that supports the processes and programs in the RRP.

• Subpart D—Review, Approval, and Retention of Risk Reduction Program Plans

Subpart D of the final rule will impose less than 1 percent of the total burden for small entities. The final requirements of this subpart are for the submission to FRA for review and approval of the initial RRP plan and any amendments thereto. Since only 10 small railroads are expected to submit RRP plans for approval in year two, and approximately 5 small railroads are expected to submit RRP plans each year thereafter, this subpart should have a very small economic impact.

• Subpart E—Internal Assessments

Subpart E of the final rule will impose approximately 9 percent of the total burden for small entities. This burden is for the ongoing cost of small railroads to perform an internal assessment and report on internal audits on an annual basis. As noted above, initially very few small railroads will be performing these internal assessments, which will serve to minimize the economic impact on small railroads.

• Subpart F—External Audits

Subpart F of the final rule will impose approximately 1 percent of the total burden for small entities. This burden is for the ongoing cost of small railroads to host an external audit by FRA or its designees on a periodic basis. This includes the burden to produce an improvement plan addressing any instances of deficiencies or noncompliance FRA identified during the audit. FRA does not expect more than five of these small railroads to receive an external audit in any given year.

Market and Competition Considerations

The railroad industry has several significant barriers to entry, such as the need to own or otherwise obtain access to rights-of-way and the high capital expenditure needed to purchase a fleet, as well as track and equipment. Furthermore, the small railroads under consideration will potentially be competing only with the trucking industry and typically deal with the transport of commodities or goods that are not truck-friendly. Thus, while this final rule will have an economic impact on Class I freight railroads and ISP railroads, it should not have an impact on the competitive position of small railroads.

For the entire railroad industry over a 10-year period, FRA estimates the total cost for the rule will be $40.2 million (PV, 7-percent), or $51.0 million (PV, 3-percent).[32] Based on information currently available, FRA estimates that Class II and Class III railroads will bear 9 percent of the total railroad costs associated with implementing the rule.

6. Description of Steps Taken To Minimize Significant Adverse Economic Impact on Small Entities

As discussed above, FRA estimates ISP railroads will incur approximately 9 percent of the total cost of this final rule. Based on FRA's RIA, the average ISP railroad will incur an average burden of approximately $18,000 (PV, 7-percent) and $21,000 (PV, 3-percent) per year. If ISP railroads complied with the RRP final rule for an average of eight years, then the average total cost will be approximately $144,000 (PV, 7-percent) and $168,000 (PV, 3-percent) per ISP railroad.

FRA has taken several steps to minimize the final rule's burden on small entities. For example, several provisions in the final rule respond directly to comments on the NPRM raising small entity concerns. Specifically, FRA modified the methodology for identifying ISP railroads to avoid over-selecting the smallest railroads and included a process in the final rule allowing railroads to appeal an ISP determination to the FRA Administrator. Additional steps FRA has taken include developing and promulgating a performance-based final rule, helping to create the Institute (which will help any small railroad comply with this rule), and providing information protections.

FRA also intends to aid railroads, including small entities, in the development of the RRPs, starting at the planning phase and continuing through the implementation phase. The final rule is also scalable by design. Therefore, a short line or regional railroad can likely maintain full compliance with the final rule with an RRP that is not likely to have the complexity and comprehensiveness of an RRP for a larger railroad. FRA will aid railroads so that the scope and content of their RRPs are proportionate to their size and the nature of their operation. All these actions benefit small railroads and will help them comply with the final rule. Lastly, as a result of addressing the safety issues that led FRA to determine the railroad demonstrated inadequate safety performance, FRA believes an RRP will help an ISP railroad more effectively

[32] FRA's estimates follow Office of Management and Budget (OMB) guidance in OMB Circular A–94 to use real discount rates of 7- and 3-percent for regulatory analysis.

allocate resources, while also reducing the frequency of accidents. For small entities, FRA estimates the monetized value of gains will be equal to or greater than the final rule's burden.

In the *Initial Regulatory Flexibility Analysis,* FRA stated it had not determined whether the proposed rule would have a significant economic impact on a substantial number of small entities. *See* 80 FR 10982 (Feb. 27, 2015). FRA remains uncertain whether the rule may have a significant impact on affected entities, or whether the number of small entities FRA expects to be impacted, a maximum of 50 out of approximately 600, is a substantial number of small entities. Therefore, FRA is not certifying that the rule will not have a significant impact on a substantial number of small entities.

In compliance with SBREFA, FRA is developing a compliance guide to assist small entities in complying with the rule. FRA is placing this guide in the public docket for this rulemaking.

Overall, FRA has taken reasonable measures to ensure the rule's impact is commensurate with business size, and FRA will aid small railroad compliance.

C. Federalism

Executive Order 13132, ''Federalism'' (64 FR 43255, Aug. 10, 1999), requires FRA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' are defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, the agency may not issue a regulation with federalism implications that imposes substantial direct compliance costs and that is not required by statute, unless the Federal Government provides the funds necessary to pay the direct compliance costs incurred by State and local governments or the agency consults with State and local government officials early in the process of developing the regulation. Where a regulation has federalism implications and preempts State law, the agency seeks to consult with State and local officials in the process of developing the regulation.

FRA analyzed this final rule under the principles and criteria in Executive Order 13132. FRA has determined this rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. In addition, FRA has determined this rule does not impose substantial direct compliance costs on State and local governments. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

This rule adds part 271, Risk Reduction Program. FRA notes that this part could have preemptive effect by the operation of law under a provision of the former Federal Railroad Safety Act of 1970, repealed and re-codified at 49 U.S.C. 20106 (section 20106). Section 20106 provides that States may not adopt or continue in effect any law, regulation, or order related to railroad safety or security that covers the subject matter of a regulation prescribed or order issued by the Secretary of Transportation (with respect to railroad safety matters) or the Secretary of Homeland Security (with respect to railroad security matters), except when the State law, regulation, or order qualifies under the ''essentially local safety or security hazard'' exception to section 20106. FRA has determined that certain State laws may be preempted by this part. Section 271.11(d) in the final rule specifically addresses the preemption of State discovery rules and sunshine laws to the extent those laws would require disclosure of information protected by § 271.11 in a Federal or State court proceeding for damages involving personal injury, wrongful death, or property damage. The preemption of State discovery rules and sunshine laws is discussed further in the section-by-section analysis of § 271.11(d). In addition, as previously discussed, section 20119(b) authorizes FRA to issue a rule governing the discovery and use of risk analysis information in litigation.

In sum, FRA has analyzed this rule under the principles and criteria in Executive Order 13132. As explained above, FRA has determined this rule has minimal federalism implications. Accordingly, FRA has determined that preparation of a federalism summary impact statement for this rule is not required.

D. International Trade Impact Assessment

The Trade Agreements Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The act requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. This rule is purely domestic in nature and is not expected to affect trade opportunities for U.S. firms doing business overseas or for foreign firms doing business in the United States.

E. Paperwork Reduction Act

FRA is submitting the information collection requirements in this rule to the Office of Management and Budget (OMB) for approval under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* The sections that contain information collection requirements are duly designated and the estimated time to fulfill each requirement is as follows:

CFR section/subject [33]	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual dollar cost equivalent [34]
271.13—Determination of inadequate safety performance (ISP)—Notice to employees of possible ISP identification by FRA.	15 railroads	5 notices	3 hours	15	$1,018
—Employee confidential comments to FRA regarding RR possible ISP identification.	125 employees	5 comments	30 minutes	2.5	170
—RR Documentation to FRA refuting possible ISP identification.	15 railroads	5 documents	8 hours	40	2,715
271.101(a)—Risk Reduction Programs (RRPs)—Class I railroads.	This burden is covered under sections 271.103, 271.105, 271.107, 271.109, and 271.111.				
271.103—RRP hazard management program (HMPs)	7 railroads	2.333 HMPs analyses	3,360 hours	7,839	532,111
271.105—RRP safety performance evaluation (SPEs): Survey/evaluation.	7 railroads	2.333 SPEs evaluation	147 hours	343	23,283

CFR section/subject [33]	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual dollar cost equivalent [34]
	7 railroads	2.333 assessments	1,060 hours	2,473	167,867
271.107—Safety Outreach—communications/reports	7 railroads	44,333 communications.	1 hour	44,333	2,379,352
	7 railroads	28 communications	30 minutes	14	950
271.109—Technology analysis and technology implementation plans.	7 railroads	2.333 reports	10 hours	23.3	1,582
271.111—RRP implementation training—programs/tr. employees/rcds.	7 railroads	1,400 records of trained employees.	3 minutes	70	4,752
271.101(c)—Communication by Class I RRs that host passenger train service with RRs subject to FRA System Safety Program Requirements.	7 railroads	40 communications/consultations.	2 hours	80	5,430
—(d)—Identification/communication w/entities performing/utilizing significant safety-related services—Class I RRs.	7 railroads	212 communications/consultations.	1 hour	212	14,391
—RR Identification/further communication with contractors performing/utilizing significant safety related services—Class I RRs.	7 railroads	1,488 communications/consultations.	1 hour	1,488	101,005
271.101(a)—Risk Reduction Programs (RRPs)—ISP railroads.	This burden is covered under sections 271.103, 271.105, 271.107, 271.109, and 271.111.				
271.103—RRP hazard management program (HMPs)	15 railroads	5 HMPs	240 hours	1,200	81,456
271.105—RRP safety performance evaluation (SPEs): Survey/evaluation.	15 railroads	5 surveys	14.73 hours	74	5,023
	15 railroads	5 SPEs	51.1 hours	256	17,377
271.107—Safety Outreach—communications/reports	15 railroads	5 communications	1 hour	5	268
	15 railroads	5 reports	3 hours	15	1,018
271.109—Technology analysis and technology implementation plans.	15 railroads	5 plans	5 hours	25	1,697
271.111—RRP implementation training—programs/tr. employees/rcds.	15 railroads	50 records of trained employees.	3 minutes	2.5	170
271.101(d)—ISPs—Identification/communication w/entities performing significant safety-related services.	15 railroads	5 communications/consultations.	2 hours	10	679
271.201/203—Written risk reduction program plans (RRP plans)—Adoption and implementation of RRP plans—Class I.	7 railroads	2.333 RRP plans	461 hours	1,075	72,971
—Written RRP plans—ISP RRs	15 railroads	5 RRP plans	96 hours	480	32,582
271.207—RR Good faith consultation w/directly affected employees—Class I RRs.	7 railroads	2.333 consults	8 hours	19	1,290
—RR Notification to non-represented employees of consultation meeting—Class I RRs.	7 railroads	1 notification	3 hours	3	204
—RR Good faith consultations/notices: ISP RRs	15 railroads	5 consults/notices	20 hours	100	6,788
(d)—Submission of detailed consultation statement along w/RRP plan by Class I RRs.	7 railroads	2.333 consultation statements.	200 hours	467	31,700
—Submission of detailed consultation statement along w/RRP plan by ISPs.	15 railroads	5 consultation statements.	40 hours	200	13,576
—Copy of RRP plan/consultation statement to service list individuals—Class I RRs + ISP RRs.	22 railroads	380 plan copies	2 minutes	12.7	862
	22 railroads	380 consultation statements.	2 minutes	12.7	862
—Statements from directly affected employees—Class I RRs.	10 labor organizations	3 statements	6 hours	18	1,222
—Statements from directly affected employees—ISP RRs.	15 railroads	12 statements	1 hour	12	815
271.301—Filing of RRP plan w/FRA—Class I RRs	7 railroads	2.333 filed plans	2 hours	5	339
—Filing of RRP plan w/FRA—ISP RRs	15 railroads	5 filed plans	2 hours	10	679
—Class I RR corrected RRP plan	7 railroads	1 RRP plan	2 hours	2	136
—FRA requested Class I RR consultation with directly affected employees regarding substantive corrections/changes to RRP plan.	7 railroads	1 consult/statement	3 hours	3	204
—ISP RR corrected RRP plan	15 railroads	1 RRP plan	2 hours	2	136
—FRA requested ISP RR further consultation with directly affected employees regarding substantive amendment to RRP plan.	15 railroads	1 consult/statement	1 hour	1	68
271.303—Amendments consultation w/directly affected employees on substantive amendments to RRP plan—Class I RRs and ISP RRs.	22 railroads (Class I + ISP).	2 consults	1 hour	2	136
—Employee statement to FRA on RR RRP plan substantive amendment where agreement could not be reached.	22 railroads (Class I + ISP).	2 employee statements.	30 minutes	1	68
—Filed amended RRP plan—Class I RRs	7 railroads	1 plan	6 hours	6	407
—Filed amended RRP plan—ISP RRs	15 railroads	1 plan	1 hour	1	68
271.307—Retention of RRP plans—Copies of RRP Plan/Amendments by RR at system/division headquarters—Class I and ISP RRs.	22 railroads (Class I + ISP).	22 plan copies	10 minutes	4	272
217.401/403—Annual internal assessment/improvement plans—Class I RRs.	7 railroads	2.333 assessments/improvement plans.	120 hours	280	19,006
—Annual internal assessment/improvement plans—ISP RRs.	15 railroads	5 assessments/improvement plans.	32 hours	160	10,861
271.405—Internal assessment report copy to FRA—Class I RRs.	7 railroads	2.333 reports	8 hours	19	1,290
—Internal assessment report copy to FRA—ISP RRs	15 railroads	5 reports	2 hours	10	679

CFR section/subject [33]	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual dollar cost equivalent [34]
Appendix B—Request by FRA for additional information/documents to determine whether railroad has met good faith and best efforts consultation requirements of section 271.207.	7 railroads	3 documents	40 hours	120	8,146
—Further railroad consultation w/employees after determination by FRA that railroad did not use good faith/best efforts.	7 railroads	1 consult	8 hours	8	543
—Meeting to discuss administrative details of consultation process during the time between initial meeting and applicability date—Class I RRs.	7 railroads	7 meetings/consults	2 hours	14	950
—Meeting to discuss administrative details of consultation process during the time between initial meeting and applicability date—ISP RRs.	15 railroads	7 meetings/consults	1 hour	7	475
—Notification to non-represented employees of good faith consultation process—ISP RRs.	15 railroads	600 notices	15 minutes	150	10,182
—Draft RRP plan proposal to employees—ISP RRs	15 railroads	20 proposals/copies	2 hours	40	2,715
—Employee comments on RRP plan draft proposal	2,000 employees	60 comments	1 hour	60	4,073
Totals	22 railroads	49,148 responses	N/A	61,825	3,566,619

All estimates include the time for reviewing instructions, searching existing data sources, gathering or maintaining the needed data, and reviewing the information.

For information or a copy of the paperwork package submitted to OMB, contact Ms. Hodan Wells, Information Collection Clearance Officer, Office of Railroad Safety, Federal Railroad Administration, at 202–493–0440 or Ms. Kimberly Toone, Information Collection Clearance Officer, Office of Information Technology, Federal Railroad Administration, at 202–493–6132.

Organizations and individuals desiring to submit comments on the collection of information requirements should direct them to Ms. Hodan Wells or Ms. Kimberly Toone, Federal Railroad Administration, 1200 New Jersey Avenue SE, 3rd Floor, Washington, DC 20590. Comments may also be submitted via email to Ms. Wells at *Hodan.Wells@dot.gov* or Ms. Toone at *Kim.Toone@dot.gov.*

OMB must make a decision concerning the collection of information requirements contained in this rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. FRA did not receive any OMB or public comments on the information collection requirements contained in the NPRM.

FRA is not authorized to impose a penalty on persons for violating information collection requirements that do not display a current OMB control number, if required. The current OMB control number is 2130–0610.

F. Environmental Assessment

FRA has evaluated this rule under its ''Procedures for Considering Environmental Impacts'' (FRA's Procedures) (64 FR 28545, May 26, 1999) as required by the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), other environmental statutes, Executive Orders, and related regulatory requirements. FRA has determined this rule is not a major FRA action (requiring the preparation of an environmental impact statement or environmental assessment) because it is categorically excluded from detailed environmental review pursuant to section 4(c)(20) of FRA's Procedures. 64 FR 28547, 28548.

Consistent with section 4(c) and (e) of FRA's Procedures, FRA also concluded that no extraordinary circumstances exist with respect to this regulation that might trigger the need for a more detailed environmental review. As a result, FRA finds this rule is not a major Federal action significantly affecting the quality of the human environment.

G. Unfunded Mandates Reform Act of 1995

Under section 201 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 2 U.S.C. 1531), each Federal agency ''shall, unless otherwise prohibited by law, assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector (other than to the extent that such regulations incorporate requirements specifically set forth in law).'' Section 202 of the Act (2 U.S.C. 1532) further requires each agency to prepare a comprehensive written statement for any proposed or final rule that includes a Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.[35]

This final rule will not result in such an expenditure, and thus preparation of such a statement is not required.

H. Energy Impact

Executive Order 13211 requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' 66 FR 28355 (May 22, 2001). FRA evaluated this final rule in accordance with Executive Order 13211, and determined that this regulatory action is not a ''significant energy action'' within the meaning of the Executive Order.

Executive Order 13783, ''Promoting Energy Independence and Economic Growth,'' requires Federal agencies to review regulations to determine whether they potentially burden the development or use of domestically produced energy resources, with particular attention to oil, natural gas, coal, and nuclear energy resources. *See* 82 FR 16093 (Mar. 31, 2017). FRA determined this final rule will not burden the development or use of domestically produced energy sources.

[33] Information collection requests relating to petitions and audits will occur outside of this information collection request timeframe. Also, because § 271.113 requires a railroad to involve directly affected employees in establishing or implementing an RRP (*e.g.,* when identifying hazards, conducting internal assessments, or otherwise performing activities required under part 271), the burdens associated with § 271.113 are covered under the other burdens associated with subparts B and E of part 271.

[34] The dollar equivalent cost is derived from the Surface Transportation Board's Full Year Wage A&B data series using the appropriate employee group hourly wage rate that includes 75-percent overhead charges.

[35] *See* U.S. Department of Transportation, ''Guidance—Threshold of Significant Regulatory Actions under the Unfunded Mandates Reform Act of 1995,'' April 4, 2016, *https://www.transportation.gov/office-policy/transportation-policy/threshold-significant-regulatory-actions-under-unfunded-mandat-0,* as accessed July 26, 2018.

Under the Executive Order, a ''significant energy action'' is defined as any action by an agency (normally published in the **Federal Register**) that promulgates, or is expected to lead to the promulgation of, a final rule or regulation (including a notice of inquiry, advance notice of proposed rulemaking, and notice of proposed rulemaking) that (1)(i) is a significant regulatory action under E.O. 12866 or any successor order and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. FRA has evaluated this rule under Executive Order 13211 and determined this rule will not have a significant adverse effect on the supply, distribution, or use of energy. Consequently, FRA has determined that this regulatory action is not a ''significant energy action'' under the Executive Order 13211.

List of Subjects in 49 CFR Part 271

Penalties, Railroad safety, Reporting and recordkeeping requirements, Risk reduction.

The Rule

■ In consideration of the foregoing, FRA adds part 271 to chapter II, subtitle B of title 49, Code of Federal Regulations, to read as follows:

PART 271—RISK REDUCTION PROGRAM

Subpart A—General

Sec.
271.1 Purpose and scope.
271.3 Application.
271.5 Definitions.
271.7 [Reserved]
271.9 Penalties and responsibility for compliance.
271.11 Discovery and admission as evidence of certain information.
271.13 Determination of inadequate safety performance.
271.15 Voluntary compliance.

Subpart B—Risk Reduction Program Requirements

271.101 Risk reduction programs.
271.103 Risk-based hazard management program.
271.105 Safety performance evaluation.
271.107 Safety outreach.
271.109 Technology analysis and technology implementation plan.
271.111 Implementation and support training.
271.113 Involvement of railroad employees.

Subpart C—Risk Reduction Program Plan Requirements

271.201 General.
271.203 Policy, purpose and scope, and goals.
271.205 System description.
271.207 Consultation requirements.
271.209 Consultation on amendments.
271.211 Risk-based hazard management program process.
271.213 Safety performance evaluation process.
271.215 Safety outreach process.
271.217 Technology implementation plan process.
271.219 Implementation and support training plan.
271.221 Involvement of railroad employees process.
271.223 Internal assessment process.
271.225 RRP implementation plan.

Subpart D—Review, Approval, and Retention of Risk Reduction Program Plans

271.301 Filing and approval.
271.303 Amendments.
271.305 Reopened review.
271.307 Retention of RRP plans.

Subpart E—Internal Assessments

271.401 Annual internal assessments.
271.403 Internal assessment improvement plans.
271.405 Internal assessment reports.

Subpart F—External Audits

271.501 External audits.
271.503 External audit improvement plans.
Appendix A to Part 271—Federal Railroad Administration Guidance on the Risk Reduction Program Consultation Process
Appendix B to Part 271—Procedures for Submission of RRP Plans and Statements From Directly Affected Employees

Authority: 49 U.S.C. 20103, 20106–20107, 20118–20119, 20156, 21301, 21304, 21311; 28 U.S.C. 2461, note; and 49 CFR 1.89.

Subpart A—General

§ 271.1 Purpose and scope.

(a) The purpose of this part is to improve railroad safety through structured, proactive processes and procedures developed and implemented by railroads. Each railroad subject to this part must establish a Risk Reduction Program (RRP) that systematically evaluates railroad safety hazards on its system and manages the risks associated with those hazards to reduce the number and rates of railroad accidents/incidents, injuries, and fatalities.

(b) This part prescribes minimum Federal safety standards for the preparation, adoption, and implementation of RRPs. This part does not restrict railroads from adopting and enforcing additional or more stringent requirements not inconsistent with this part.

(c) This part prescribes the protection of information a railroad compiles or collects solely for the purpose of planning, implementing, or evaluating an RRP under this part.

(d) This part does not require an RRP to address hazards completely unrelated to railroad safety and that fall under the exclusive jurisdiction of another Federal agency. Additionally, an RRP required by this part is not intended to address and should not address the safety of employees while performing inspections, tests, and maintenance, except where FRA has already addressed workplace safety issues, such as blue signal protection in part 218 of this chapter. FRA does not intend to approve any specific portion of an RRP plan that relates exclusively to employee working conditions.

§ 271.3 Application.

(a) Except as provided in paragraph (b) of this section, this part applies to—

(1) Class I railroads;

(2) Railroads determined to have inadequate safety performance pursuant to § 271.13; and

(3) Railroads that voluntarily comply with the requirements of this part pursuant to § 271.15.

(b) This part does not apply to:

(1) Rapid transit operations in an urban area that are not connected to the general railroad system of transportation;

(2) Tourist, scenic, historic, or excursion operations, whether on or off the general railroad system of transportation;

(3) Operation of private cars, including business/office cars and circus trains;

(4) Railroads that operate only on track inside an installation that is not part of the general railroad system of transportation (*i.e.,* plant railroads, as defined in § 271.5); and

(5) Commuter or intercity passenger railroads that are subject to Federal system safety program requirements contained in part 270 of this chapter.

(c) If a railroad contracts out significant portions of its operations, the contractor and the contractor's employees performing the railroad's operations shall be considered directly affected employees for purposes of this part.

§ 271.5 Definitions.

As used in this part only—

Accident/incident means an ''accident/incident'' as defined in § 225.5 of this chapter.

Administrator means the Administrator of the Federal Railroad Administration or the Administrator's delegate.

FRA means the Federal Railroad Administration.

FRA Associate Administrator means the Associate Administrator for Railroad

Safety and Chief Safety Officer, Federal Railroad Administration, or the Associate Administrator's delegate.

Fully implemented means that all elements of an RRP as described in the RRP plan are established and applied to the safety management of the railroad.

Hazard means any real or potential condition that can cause injury, illness, or death; damage to or loss of a system, equipment, or property; or damage to the environment.

Inadequate safety performance means safety performance that FRA has determined to be inadequate based on the criteria described in § 271.13.

Mitigation strategy means an action or program intended to reduce or eliminate the risk associated with a hazard.

Person means an entity of any type covered under 1 U.S.C. 1, including, but not limited to, the following: A railroad; a manager, supervisor, official, or other employee or agent of a railroad; any owner, manufacturer, lessor, or lessee of railroad equipment, track, or facilities; any independent contractor or subcontractor providing goods or services to a railroad; and any employee of such owner, manufacturer, lessor, lessee, or independent contractor or subcontractor.

Pilot project means a limited scope project used to determine whether quantitative evaluation and analysis suggests that a particular system or mitigation strategy has potential to succeed on a full-scale basis.

Plant railroad means a plant or installation that owns or leases a locomotive, uses that locomotive to switch cars throughout the plant or installation, and is moving goods solely for use in the facility's own industrial processes. The plant or installation could include track immediately adjacent to the plant or installation if the plant railroad leases the track from the general system railroad and the lease provides for (and actual practice entails) the exclusive use of that trackage by the plant railroad and the general system railroad for purposes of moving only cars shipped to or from the plant. A plant or installation that operates a locomotive to switch or move cars for other entities, even if solely within the confines of the plant or installation, rather than for its own purposes or industrial processes, is not considered a plant railroad because the performance of such activity makes the operation part of the general railroad system of transportation.

Positive train control system means a system designed to prevent train-to-train collisions, overspeed derailments, incursions into established work zone limits, and the movement of a train through a switch left in the wrong position, as described in subpart I of part 236 of this chapter.

Railroad means:

(1) Any form of non-highway ground transportation that runs on rails or electromagnetic guideways, including:

(i) Commuter or other short-haul rail passenger service in a metropolitan or suburban area and commuter railroad service that was operated by the Consolidated Rail Corporation on January 1, 1979; and

(ii) High speed ground transportation systems that connect metropolitan areas, without regard to whether those systems use new technologies not associated with traditional railroads, but does not include rapid transit operations in an urban area that are not connected to the general railroad system of transportation; and

(2) A person or organization that provides railroad transportation, whether directly or by contracting out operation of the railroad to another person.

Risk means the combination of the probability (or frequency of occurrence) and the consequence (or severity) of a hazard.

Risk-based HMP means a risk-based hazard management program (HMP).

Risk reduction means the formal, top-down, organization-wide approach to managing safety risk and assuring the effectiveness of safety risk mitigation strategies. It includes systematic procedures, practices, and policies for the management of safety risk.

RRP means a Risk Reduction Program.

RRP plan means a Risk Reduction Program plan.

Safety culture means the shared values, actions, and behaviors that demonstrate a commitment to safety over competing goals and demands.

Safety performance means a realized or actual safety accomplishment relative to stated safety objectives.

Safety outreach means the communication of safety information to support the implementation of an RRP throughout a railroad.

Senior management means personnel at the highest level of a railroad's management who are responsible for making major policy decisions and long-term business plans regarding the operation of the railroad.

STB means the Surface Transportation Board of the United States.

Tourist, scenic, historic, or excursion operations means railroad operations that carry passengers, often using antiquated equipment, with the conveyance of the passengers to a particular destination not being the principal purpose. Train movements of new passenger equipment for demonstration purposes are not tourist, scenic, historic, or excursion operations.

§ 271.7 [Reserved]

§ 271.9 Penalties and responsibility for compliance.

(a) Any person that violates any requirement of this part or causes the violation of any such requirement is subject to a civil penalty of at least the minimum civil monetary penalty and not more than the ordinary maximum civil monetary penalty per violation, except that: Penalties may be assessed against individuals only for willful violations, and, where a grossly negligent violation or a pattern of repeated violations has created an imminent hazard of death or injury to individuals, or has caused death or injury, a penalty not to exceed the aggravated maximum civil monetary penalty per violation may be assessed. *See* 49 CFR part 209, appendix A. Each day a violation continues shall constitute a separate offense. Any person that knowingly and willfully falsifies a record or report required by this part may be subject to criminal penalties under 49 U.S.C. 21311. See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

(b) Although the requirements of this part are stated in terms of the duty of a railroad, when any person, including a contractor or subcontractor to a railroad, performs any function covered by this part, that person (whether or not a railroad) shall perform that function in accordance with this part.

§ 271.11 Discovery and admission as evidence of certain information.

(a) *Protected information.* Any information compiled or collected after February 17, 2021 solely for the purpose of planning, implementing, or evaluating a risk reduction program under this part shall not be subject to discovery, admitted into evidence, or considered for other purposes in a Federal or State court proceeding for damages involving personal injury, wrongful death, or property damage. For purposes of this section—

(1) ''Information'' includes plans, reports, documents, surveys, schedules, lists, or data, and specifically includes a railroad's analysis of its safety risks under § 271.103(b) and a railroad's statement of mitigation measures under § 271.103(c); and

(2) ''Solely'' means that a railroad originally compiled or collected the information for the exclusive purpose of planning, implementing, or evaluating a risk reduction program under this part.

Information compiled or collected for any other purpose is not protected, even if the railroad also uses that information for a risk reduction program. ''Solely'' also means a railroad continues to use that information only for its risk reduction program. If a railroad subsequently uses for any other purpose information that was initially compiled or collected for a risk reduction program, this section does not protect that information to the extent that it is used for the non-risk reduction program purpose. The use of that information within the railroad's risk reduction program, however, remains protected. This section does not protect information that is required to be compiled or collected pursuant to any other provision of law or regulation.

(b) *Non-protected information.* This section does not affect the discovery, admissibility, or consideration for other purposes in a Federal or State court proceeding for damages involving personal injury, wrongful death, or property damage of information compiled or collected for a purpose other than that specifically identified in paragraph (a) of this section. Such information shall continue to be discoverable, admissible, or considered for other purposes in a Federal or State court proceeding for damages involving personal injury, wrongful death, or property damage if it was discoverable, admissible, or considered for other purposes in a Federal or State court proceeding for damages involving personal injury, wrongful death, or property damage on or before February 17, 2021. Specifically, the types of information not affected by this section include:

(1) Information compiled or collected on or before February 17, 2021;

(2) Information compiled or collected on or before February 17, 2021 and that continues to be compiled or collected, even if used to plan, implement, or evaluate a railroad's risk reduction program; or

(3) Information that is compiled or collected after February 17, 2021, and is compiled or collected for a purpose other than that identified in paragraph (a) of this section.

(c) *Information protected by other law or regulation.* Nothing in this section shall affect or abridge in any way any other protection of information provided by another provision of law or regulation. Any such provision of law or regulation applies independently of the protections provided by this section.

(d) *Preemption.* To the extent that State discovery rules and sunshine laws would require disclosure of information protected by this section in a Federal or State court proceeding for damages involving personal injury, wrongful death, or property damage, those rules and laws are preempted.

(e) *Enforcement.* This section does not apply to civil or criminal law enforcement proceedings.

§ 271.13 Determination of inadequate safety performance.

(a) *General.* (1) This section describes FRA's methodology for determining which railroads shall establish an RRP because they have inadequate safety performance. FRA's methodology consists of a two-phase annual analysis, comprised of both a quantitative analysis and qualitative assessment. FRA's methodology analyzes all railroads except for:

(i) Railroads excluded from this part under § 271.3(b);

(ii) Railroads already required to comply with this part;

(iii) Railroads that are voluntarily complying with this part under § 271.15; and

(iv) Except as provided in paragraph (a)(2) of this section, new start-up railroads that have reported accident/incident data to FRA pursuant to part 225 of this chapter for fewer than three years.

(2) Notwithstanding paragraph (a)(1)(iv) of this section, railroads formed through amalgamation of operations (for example, railroads formed through consolidations, mergers, or acquisitions of control) are included in the analysis using the combined data of the pre-amalgamation entities.

(b) *Quantitative analysis*—(1) *Methodology.* The first phase of FRA's annual analysis is a statistically-based quantitative analysis of each railroad within the scope of the analysis, using historical safety data maintained by FRA for the three most recent full calendar years. The purpose of the quantitative analysis is to make a threshold identification of railroads that possibly have inadequate safety performance. The quantitative analysis consists of a preliminary selection and a rate-based analysis. Only railroads that the preliminary selection identifies will proceed to the rate-based analysis.

(i) The preliminary selection calculates the following values:

(A) A railroad's number of worker on duty fatalities during the 3-year period, calculated using ''Worker on Duty-Railroad Employee (Class A),'' ''Worker on Duty-Contractor (Class F),'' and ''Worker on Duty-Volunteer (Class H)'' information reported on FRA Form 6180.55 pursuant to FRA's accident/incident reporting regulations in part 225 of this chapter; and

(B) The sum total of a railroad's number of worker on duty injuries/illnesses during the 3-year period (calculated using ''Worker on Duty-Railroad Employee (Class A),'' ''Worker on Duty-Contractor (Class F),'' and ''Worker on Duty-Volunteer (Class H)'' information reported on FRA Form 6180.55 pursuant to FRA's accident/incident reporting regulations in part 225 of this chapter) added to the number of rail equipment accidents/incidents during the 3-year period (calculated using information reported on FRA Forms 6180.54 and 6180.55 pursuant to FRA's accident/incident reporting regulations in part 225 of this chapter).

(ii) For railroads that the preliminary selection identifies, as described in paragraph (b)(2)(i) of this section, the rate-based analysis calculates the following three factors:

(A) A railroad's number of worker on duty fatalities during the 3-year period, calculated using ''Worker on Duty-Railroad Employee (Class A),'' ''Worker on Duty-Contractor (Class F),'' and ''Worker on Duty-Volunteer (Class H)'' information reported on FRA Form 6180.55 pursuant to FRA's accident/incident reporting regulations in part 225 of this chapter;

(B) A railroad's on duty employee injury/illness rate, calculated using ''Worker on Duty-Railroad Employee (Class A),'' ''Worker on Duty-Contractor (Class F),'' and ''Worker on Duty-Volunteer (Class H)'' information reported on FRA Form 6180.55 pursuant to FRA's accident/incident reporting regulations in part 225 of this chapter. FRA calculates this rate using the following formula, which gives the rate of employee injuries/illnesses per 200,000 employee hours over a 3-year period:

Injury/Illness Rate = (Total FRA Reportable Worker On Duty Injuries + Total FRA Reportable On Duty Employee Illnesses over a 3-year Period)/(Total Employee Hours over a 3-year Period/200,000); and

(C) A railroad's rail equipment accident/incident rate, calculated using information reported on FRA Forms 6180.54 and 6180.55 pursuant to FRA's accident/incident reporting regulations in part 225 of this chapter. FRA calculates this rate using the following formula, which gives the rate of rail equipment accidents/incidents per 1,000,000 train miles operated over a 3-year period:

Rail Equipment Accident/Incident Rate = Total FRA Reportable Rail Equipment Accidents/Incidents over a 3-year Period/(Total Train

Miles over a 3-year Period/ 1,000,000)

(2) *Identification.* (i) The preliminary selection phase of the quantitative analysis identifies railroads for further analysis in the rate-based analysis if at least one of the following two conditions exist within the scope and timeframe of the analysis:

(A) A railroad has one or more worker on duty fatalities as calculated in paragraph (b)(1)(i)(A) of this section; or

(B) A railroad is at or above the 90th percentile for the sum total of worker on duty injuries/illnesses and rail equipment accidents/incidents, as calculated in paragraph (b)(1)(i)(B) of this section.

(ii) For railroads identified in the preliminary selection, the rate-based analysis identifies railroads as possibly having inadequate safety performance if at least one of the following two conditions exists within the scope and time frame of the analysis:

(A) A railroad has one or more worker on duty fatalities as calculated in paragraph (b)(1)(ii)(A) of this section; or

(B) A railroad is at or above the 90th percentile of railroads identified in the preliminary selection in either of the factors described in paragraphs (b)(1)(ii)(B) and (C) of this section.

(c) *Qualitative assessment.* The second phase of FRA's analysis is a qualitative assessment of railroads identified in the quantitative analysis as possibly having inadequate safety performance.

(1) *Notification and railroad/ employee comment.* FRA will notify a railroad in writing if FRA conducts a qualitative assessment of the railroad because the quantitative analysis identified the railroad as possibly having inadequate safety performance.

(i) No later than 15 days after receiving FRA's written notice, a railroad shall notify its employees of FRA's written notice. The railroad shall post this employee notification at all locations where the railroad reasonably expects its employees to report and to have an opportunity to observe the notice. The railroad shall post and continuously display the employee notification until 45 days after FRA's initial written notice. The railroad shall notify employees who do not have a regular on-duty point for reporting to work by other means, under the railroad's standard practice for communicating with employees. The notification shall inform railroad employees that they may confidentially submit comments to FRA regarding the railroad's safety performance and that employees shall file any such comments with the FRA Associate Administrator for Railroad Safety and Chief Safety Officer, 1200 New Jersey Avenue SE, Washington, DC 20590 no later than 45 days following FRA's initial written notice.

(ii) No later than 45 days after receiving FRA's written notice, a railroad may provide FRA documentation supporting any claims that the railroad does not have inadequate safety performance.

(2) *Methodology.* No later than 90 days after providing the initial notice to a railroad identified by the quantitative analysis, FRA will conduct a qualitative assessment of the identified railroad and make a final determination regarding whether it has inadequate safety performance. The qualitative assessment will consider any documentation provided by the railroad, comments submitted by railroad employees, and any other pertinent information, including information regarding violations FRA has issued against the railroad.

(d) *Final notification.* For each railroad that FRA provides an initial written notice, FRA will provide a final written notice informing the railroad whether or not FRA determines that the railroad has demonstrated inadequate safety performance.

(e) *Compliance.* (1) A railroad with inadequate safety performance shall develop and implement an RRP meeting the requirements of this part and submit an RRP plan meeting the filing and timing requirements in § 271.301.

(2) A railroad with inadequate safety performance must comply with the requirements of this part for a minimum of five years from the date FRA approves the railroad's RRP plan under subpart D of this part.

(f) *Petition for reconsideration of inadequate safety performance determination.* (1) To appeal a final written notice under paragraph (d) of this section, a railroad shall file a petition for reconsideration with the Administrator. To file a petition, the railroad must:

(i) File the petition no later than 30 days after the date the railroad receives FRA's final written notice under paragraph (d) of this section informing the railroad that it has demonstrated inadequate safety performance; and

(ii) File the petition in accordance with the procedures in §§ 211.7(b)(1) and 211.57 of this chapter.

(2) FRA will process petitions under § 211.59 of this chapter.

(g) *Petition to discontinue compliance with this part.* After the five-year compliance period, the railroad may petition FRA for approval to discontinue compliance with this part. A railroad shall file a petition, and FRA will process the petition, under the procedures contained in § 211.41 of this chapter. When processing a petition, FRA will reevaluate the railroad's safety performance to determine whether the railroad's RRP has resulted in significant and sustained safety improvements, and whether these measured improvements are likely sustainable in the long term. FRA's evaluation will include a quantitative analysis as described in paragraph (b) of this section, although FRA will not automatically grant a petition to discontinue compliance if the quantitative analysis results do not meet the identification thresholds described in paragraph (b)(2) of this section. For all petitions under this section, FRA will also examine qualitative factors and review information from FRA RRP audits and other relevant sources.

§ 271.15 Voluntary compliance.

(a) *General.* A railroad not otherwise subject to this part may voluntarily comply by establishing and fully implementing an RRP meeting the requirements of this part. A voluntary RRP shall be supported by an RRP plan that has been submitted to FRA for approval pursuant to the requirements of subpart D of this part. After FRA has approved its RRP plan, a voluntarily-compliant railroad that fails to comply with the requirements of this part is subject to civil penalties or other FRA enforcement action.

(b) *Duration.* A voluntarily-compliant railroad will be required to comply with the requirements of this part for a minimum period of five years, running from the date on which FRA approves the railroad's plan pursuant to subpart D of this part.

(c) *Notification to discontinue compliance.* After this five-year period, a voluntarily-compliant railroad may discontinue compliance with this part by providing written notice to the FRA Associate Administrator for Railroad Safety and Chief Safety Officer, 1200 New Jersey Avenue SE, Washington, DC 20590.

(d) *Discovery and admission as evidence of certain information.* The information protection provisions in § 271.11 apply to information compiled or collected pursuant to a voluntary RRP that is conducted in accordance with the requirements of this part and as provided by § 271.301(b)(4)(ii).

Subpart B—Risk Reduction Program Requirements

§ 271.101 Risk reduction programs.

(a) *Program required.* Each railroad shall establish and fully implement an RRP meeting the requirements of this part. An RRP shall systematically evaluate railroad safety hazards on a railroad's system and manage the resulting risks to reduce the number and rates of railroad accidents/incidents, injuries, and fatalities. An RRP is an ongoing program that supports continuous safety improvement. A railroad shall design its RRP so that it promotes and supports a positive safety culture at the railroad. An RRP shall include the following:

(1) A risk-based hazard management program, as described in § 271.103;

(2) A safety performance evaluation component, as described in § 271.105;

(3) A safety outreach component, as described in § 271.107;

(4) A technology analysis and technology implementation plan, as described in § 271.109;

(5) RRP implementation and support training, as described in § 271.111; and

(6) Involvement of railroad employees in the establishment and implementation of an RRP, as described in § 271.113.

(b) *RRP plans.* A railroad's RRP shall be supported by an FRA-approved RRP plan meeting the requirements of subpart C of this part.

(c) *Host railroads and system safety programs.* (1) If a railroad subject to this part (RRP railroad) hosts passenger train service for a railroad subject to the system safety program requirements in part 270 of this title (system safety program (SSP) railroad), the RRP railroad shall communicate with the SSP railroad to coordinate the portions of the system safety program applicable to the RRP railroad hosting the passenger train service.

(2) The RRP railroad shall incorporate its communication and coordination with the SSP railroad into its own RRP.

(d) *Persons that perform or utilize significant safety-related services.* Under § 271.205(a)(3), a railroad's RRP plan shall identify persons that enter into a contractual relationship with the railroad to either perform significant safety-related services on the railroad's behalf or to utilize significant safety-related services provided by the railroad for railroad operations purposes. For example, a railroad's RRP plan shall identify entities such as host railroads, contract operators, shared track/corridor operators, or other contractors utilizing or performing significant safety-related services. A railroad shall identify such persons even if the persons are not required to comply with this part (*e.g.,* a railroad shall identify a tourist railroad that operates over the railroad's track even though the tourist railroad is exempt from this rule under § 271.3(b)(2)). A railroad shall ensure persons performing or utilizing significant safety-related services support and participate in its RRP.

§ 271.103 Risk-based hazard management program.

(a) *General.* (1) An RRP shall include an integrated, system-wide, and ongoing risk-based HMP that proactively identifies hazards and mitigates the risks resulting from those hazards.

(2) A risk-based HMP shall be fully implemented (*i.e.,* activities initiated) within 36 months after FRA approves a railroad's RRP plan pursuant to § 271.301(d).

(b) *Risk-based hazard analysis.* As part of its risk-based HMP, a railroad shall conduct a risk-based hazard analysis that addresses, at a minimum, the following aspects of a railroad's system: Infrastructure; equipment; employee levels and work schedules; operating rules and practices; management structure; employee training; and other areas impacting railroad safety that are not covered by railroad safety laws or regulations or other Federal laws or regulations. A railroad shall make the results of its risk-based hazard analysis available to FRA upon request. At a minimum, a risk-based hazard analysis shall:

(1) Identify hazards by analyzing:

(i) Aspects of the railroad's system, including any operational changes, system extensions, or system modifications; and

(ii) Accidents/incidents, injuries, fatalities, and other known indicators of hazards;

(2) Calculate risk by determining and analyzing the likelihood and severity of potential events associated with identified risk-based hazards; and

(3) Compare and prioritize the identified risks for mitigation purposes.

(c) *Mitigation strategies.* (1) As part of its risk-based HMP, a railroad shall design and implement mitigation strategies that improve safety by:

(i) Mitigating or eliminating aspects of a railroad's system that increase risks identified in the risk-based hazard analysis; and

(ii) Enhancing aspects of a railroad's system that decrease risks identified in the risk-based hazard analysis.

(2) A railroad may use pilot projects, including pilot projects conducted by other railroads, to determine whether quantitative data suggests that a particular mitigation strategy has potential to succeed on a full-scale basis.

§ 271.105 Safety performance evaluation.

(a) *General.* As part of its RRP, a railroad shall develop and maintain ongoing processes and systems for evaluating the safety performance of its system and identifying and analyzing its safety culture. A railroad's safety performance evaluation shall consist of both a safety monitoring and a safety assessment component.

(b) *Safety monitoring.* A railroad shall monitor the safety performance of its system by, at a minimum, establishing processes and systems to acquire safety data and information from the following sources:

(1) Continuous monitoring of operational processes and systems (including any operational changes, system extensions, or system modifications);

(2) Periodic monitoring of the operational environment to detect changes that may generate new hazards;

(3) Investigations of accidents/incidents, injuries, fatalities, and other known indicators of hazards;

(4) Investigations of reports regarding potential non-compliance with Federal railroad safety laws or regulations, railroad operating rules and practices, or mitigation strategies established by the railroad; and

(5) A reporting system through which employees can report safety concerns (including, but not limited to, hazards, issues, occurrences, and incidents) and propose safety solutions and improvements.

(c) *Safety assessment.* To assess the need for changes to a railroad's mitigation strategies or overall RRP, a railroad shall establish processes to analyze the data and information collected pursuant to paragraph (b) of this section (as well as any other relevant data regarding its operations, products, and services). At a minimum, this assessment shall:

(1) Evaluate the overall effectiveness of the railroad's RRP in reducing the number and rates of railroad accidents/incidents, injuries, and fatalities;

(2) Evaluate the effectiveness of the railroad's RRP in meeting the goals described by its RRP plan (see § 271.203(c));

(3) Evaluate the effectiveness of risk mitigations in reducing the risk associated with an identified hazard. Any hazards associated with ineffective mitigation strategies shall be reevaluated through the railroad's risk-based HMP, as described in § 271.103; and

(4) Identify new, potential, or previously unknown hazards, which shall then be evaluated by the railroad's risk-based HMP, as described in § 271.103.

§ 271.107 Safety outreach.

(a) *Outreach.* An RRP shall include a safety outreach component that communicates RRP safety information to railroad personnel (including contractors) as that information is relevant to their positions. At a minimum, a safety outreach program shall:

(1) Convey safety-critical information;

(2) Explain why RRP-related safety actions are taken; and

(3) Explain why safety procedures are introduced or changed.

(b) *Reporting to management.* The status of risk-based HMP activities shall be reported to railroad senior management on an ongoing basis.

§ 271.109 Technology analysis and technology implementation plan.

(a) *General.* As part of its RRP, a Class I railroad shall conduct a technology analysis and develop and adopt a technology implementation plan no later than February 17, 2023. A railroad with inadequate safety performance shall conduct a technology analysis and develop and adopt a technology implementation plan no later than three years after receiving final written notification from FRA to comply with this part, pursuant to § 271.13(d), or no later than February 17, 2023, whichever is later. A railroad that the STB reclassifies or newly classifies as a Class I railroad shall conduct a technology analysis and develop and adopt a technology implementation plan no later than three years following the effective date of the classification or reclassification or no later than April 18, 2023, whichever is later. A voluntarily-compliant railroad shall conduct a technology analysis and develop and adopt a technology implementation plan no later than three years after FRA approves the railroad's RRP plan.

(b) *Technology analysis.* A technology analysis shall evaluate current, new, or novel technologies that may mitigate or eliminate hazards and the resulting risks identified through the risk-based HMP. The railroad shall analyze the safety impact, feasibility, and costs and benefits of implementing technologies that will mitigate or eliminate hazards and the resulting risks. At a minimum, the technologies a railroad shall consider as part of its technology analysis are: Processor-based technologies, positive train control systems, electronically-controlled pneumatic brakes, rail integrity inspection systems, rail integrity warning systems, switch position monitors and indicators, trespasser prevention technology, and highway-rail grade crossing warning and protection technology.

(c) *Technology implementation plan.* A railroad shall develop, and periodically update as necessary, a technology implementation plan that contains a prioritized implementation schedule describing the railroad's plan for development, adoption, implementation, maintenance, and use of current, new, or novel technologies on its system over a 10-year period to reduce safety risks identified in the railroad's risk-based HMP.

(d) *Positive train control.* Except as required by subpart I of part 236 of this chapter, if a railroad decides to implement positive train control systems as part of its technology analysis and implementation plan, the railroad shall set forth and comply with a schedule for implementation of the positive train control system consistent with the deadlines in the Positive Train Control Enforcement and Implementation Act of 2015, Public Law 114–73, 129 Stat. 576–82 (Oct. 29, 2015), and 49 CFR 236.1005(b)(7).

§ 271.111 Implementation and support training.

(a) A railroad shall provide RRP training to each employee, including an employee of any person identified by the railroad's RRP plan pursuant to § 271.205(a)(3) as performing significant safety-related services on the railroad's behalf or utilizing significant safety-related services provided by the railroad, who has significant responsibility for implementing and supporting the railroad's RRP. This training shall help ensure that all personnel with significant responsibility for implementing and supporting the RRP understand the goals of the program, are familiar with the elements of the railroad's program, and have the requisite knowledge and skills to fulfill their responsibilities under the program.

(b) A railroad shall keep a record of training conducted under this section and update that record as necessary. A railroad shall make training records available for inspection and copying upon the request of representatives of FRA or States participating under part 212 of this chapter.

(c) Training under this section may include, but is not limited to, interactive computer-based training, video conferencing, or formal classroom training.

§ 271.113 Involvement of railroad employees.

(a) An RRP shall involve a railroad's directly affected employees in the establishment and implementation of the RRP.

(b) For example, a railroad must have a process for involving directly affected employees when identifying hazards, developing and implementing mitigation strategies, conducting internal annual assessments, or otherwise performing actions required by this part.

Subpart C—Risk Reduction Program Plan Requirements

§ 271.201 General.

A railroad shall adopt and implement its RRP through a written RRP plan containing the elements described in this subpart. A railroad's RRP plan shall be approved by FRA according to the requirements contained in subpart D of this part.

§ 271.203 Policy, purpose and scope, and goals.

(a) *Policy statement.* An RRP plan shall contain a policy statement endorsing the railroad's RRP. This statement shall be signed by the chief official at the railroad (*e.g.,* chief executive officer).

(b) *Purpose and scope.* An RRP plan shall contain a statement describing the purpose and scope of the railroad's RRP. This purpose and scope statement shall describe:

(1) The railroad's safety philosophy and safety culture;

(2) How the railroad promotes improvements to its safety culture; and

(3) The roles and responsibilities of railroad personnel (including management) within the railroad's RRP.

(c) *Goals.* An RRP plan shall contain a statement that defines the specific goals of the RRP and describes clear strategies for reaching those goals. These goals shall be long-term, meaningful, measurable, and focused on the mitigation of risks arising from identified safety hazards.

§ 271.205 System description.

(a) An RRP plan shall contain a description of the characteristics of the railroad's system. At a minimum, the system description shall:

(1) Support the identification of hazards by establishing a basic understanding of the scope of the railroad's system;

(2) Include components briefly describing the railroad's history, operations, scope of service, maintenance, physical plant, and system requirements;

(3) Identify all persons that enter into a contractual relationship with the railroad to either perform significant safety-related services on the railroad's behalf or to utilize significant safety-related services provided by the railroad for railroad operations purposes. For example, a railroad's RRP plan shall identify entities such as host railroads, contract operators, shared track/corridor operators, or other contractors utilizing or performing significant safety-related services. A railroad shall identify such persons even if the persons are not required to comply with this part (*e.g.,* a railroad shall identify a tourist railroad that operates over the railroad's track even though the tourist railroad is exempt from this part pursuant to § 271.3(b)(2)); and

(4) Describe how the railroad will ensure that any persons identified pursuant to paragraph (a)(3) of this section will support and participate in the railroad's RRP. For example, the system description shall describe the extent to which such persons will, as part of the railroad's RRP, assist in identifying hazards, developing and implementing mitigation strategies, conducting internal annual assessments, or otherwise performing actions required by this part.

(b) [Reserved]

§ 271.207 Consultation requirements.

(a) *General duty.* (1) Each railroad required to establish an RRP under this part shall in good faith consult with, and use its best efforts to reach agreement with, all of its directly affected employees, including any non-profit labor organization representing a class or craft of directly affected employees, on the contents of the RRP plan.

(2) A railroad that consults with a non-profit employee labor organization is considered to have consulted with the directly affected employees represented by that organization.

(b) *Preliminary meeting.* A railroad shall have a preliminary meeting with its directly affected employees to discuss how the consultation process will proceed. A railroad is not required to discuss the substance of an RRP plan during this preliminary meeting.

(1) A Class I railroad shall meet no later than October 15, 2020 with its directly affected employees to discuss the consultation process. The Class I railroad shall notify the directly affected employees of this meeting no less than 60 days before it is scheduled.

(2) A railroad determined to have inadequate safety performance shall meet no later than 30 days following FRA's notification with its directly affected employees to discuss the consultation process. The inadequate safety performance railroad shall notify the directly affected employees of this meeting no less than 15 days before it is scheduled.

(3) A railroad that the STB reclassifies or newly classifies as a Class I railroad shall meet with its directly affected employees to discuss the consultation process no later than 30 days following the effective date of the classification or reclassification. The reclassified or newly classified Class I railroad shall notify the directly affected employees of this meeting no less than 15 days before it is scheduled.

(4) A voluntarily-compliant railroad that files a notification with FRA of its intent to file an RRP plan under § 271.301(b)(4)(i) shall meet with its directly affected employees to discuss the consultation process no later than 30 days following the date that the railroad filed the notification. The voluntarily-compliant railroad shall notify the directly affected employees of this meeting no less than 15 days before it is scheduled.

(5) Compliance with the mandatory preliminary meeting requirements of this paragraph (b) does not constitute full compliance with the consultation requirements of this section.

(c) *Guidance.* Appendix A to this part contains guidance on how a railroad could comply with the requirements of this section.

(d) *Railroad consultation statements.* A railroad required to submit an RRP plan under § 271.301 shall also submit, together with that plan, a consultation statement that includes the following information:

(1) A detailed description of the process the railroad utilized to consult with its directly affected employees;

(2) If the railroad could not reach agreement with its directly affected employees on the contents of its RRP plan, identification of any known areas of non-agreement and an explanation why it believes agreement was not reached; and

(3) A service list containing the names and contact information for each international/national president of any non-profit employee labor organization representing a class or craft of the railroad's directly affected employees. The service list must also contain the name and contact information for any directly affected employee who significantly participated in the consultation process independently of a non-profit employee labor organization. If an international/national president did not participate in the consultation process, the service list shall also contain the name and contact information for a designated representative who participated on his or her behalf. When a railroad submits its RRP plan and consultation statement to FRA under § 271.301, it shall also simultaneously send a copy of these documents to all individuals identified in the service list. A railroad may send the documents to the identified individuals via electronic means or other service means reasonably calculated to succeed.

(e) *Statements from directly affected employees.* (1) If a railroad and its directly affected employees cannot reach agreement on the proposed contents of an RRP plan, the directly affected employees may file a statement explaining their views on the plan on which agreement was not reached with the FRA Associate Administrator for Railroad Safety and Chief Safety Officer, 1200 New Jersey Avenue SE, Washington, DC 20590. The FRA Associate Administrator shall consider any such views during the plan review and approval process.

(2) A railroad's directly affected employees have 30 days following the railroad's submission of a proposed RRP plan to submit the statement described in paragraph (e)(1) of this section.

§ 271.209 Consultation on amendments.

A railroad's RRP plan shall include a description of the process the railroad will use to consult with its directly affected employees on any subsequent substantive amendments to the railroad's RRP plan. The requirements of this section do not apply to non-substantive amendments (*e.g.,* amendments that update names and addresses of railroad personnel).

§ 271.211 Risk-based hazard management program process.

(a) *Risk-based hazard analysis.* An RRP plan shall describe the railroad's method for conducting its risk-based hazard analysis pursuant to § 271.103(b). At a minimum, the description shall specify:

(1) The processes the railroad will use to identify hazards and the risks associated with those hazards;

(2) The sources the railroad will use to support the ongoing identification of hazards and the risks associated with those hazards; and

(3) The processes the railroad will use to compare and prioritize identified risks for mitigation purposes.

(b) *Mitigation strategies.* An RRP plan shall describe the railroad's processes for designing and implementing mitigation strategies pursuant to § 271.103(c). At a minimum, the

description shall specify the railroad's processes for:

(1) Identifying and selecting mitigation strategies; and

(2) Monitoring an identified hazard through the mitigation of the risk associated with that hazard.

§ 271.213 Safety performance evaluation process.

An RRP plan shall describe a railroad's processes for identifying and analyzing its safety culture pursuant to § 271.105(a), monitoring safety performance pursuant to § 271.105(b), and conducting safety assessments pursuant to § 271.105(c).

§ 271.215 Safety outreach process.

An RRP plan shall describe a railroad's processes for communicating safety information to railroad personnel and management pursuant to § 271.107.

§ 271.217 Technology implementation plan process.

(a) An RRP plan shall contain a description of the railroad's processes for:

(1) Conducting a technology analysis pursuant to § 271.109(b); and

(2) Developing a technology implementation plan pursuant to § 271.109(c).

(b) [Reserved]

§ 271.219 Implementation and support training plan.

(a) An RRP plan shall contain a training plan describing the railroad's processes, pursuant to § 271.111, for training employees with significant responsibility for implementing and supporting the RRP (including employees of a person identified pursuant to § 271.205(a)(3) as performing significant safety-related services on the railroad's behalf or utilizing significant safety-related services provided by the railroad for railroad operations purposes who have significant responsibility for implementing and supporting the railroad's RRP).

(b) The training plan shall describe the content of the RRP training for each position or job function identified pursuant to § 271.225(b)(3) as having significant responsibilities for implementing the RRP.

§ 271.221 Involvement of railroad employees process.

An RRP plan shall contain a description of the railroad's processes for involving railroad employees in the establishment and implementation of an RRP pursuant to § 271.113. If a railroad contracts out significant portions of its operations, the contractor and the contractor's employees performing the railroad's operations shall be considered employees for the purposes of this section.

§ 271.223 Internal assessment process.

(a) An RRP plan shall describe the railroad's processes for conducting an internal assessment of its RRP pursuant to subpart E of this part. At a minimum, this description shall contain the railroad's processes used to:

(1) Conduct an internal assessment of its RRP;

(2) Internally report the results of its internal assessment to railroad senior management; and

(3) Develop improvement plans, including developing and monitoring recommended improvements (including any necessary revisions or updates to the RRP plan) for fully implementing the railroad's RRP, complying with the implemented elements of the RRP plan, or achieving the goals identified in the railroad's RRP plan pursuant to § 271.203(c).

(b) [Reserved]

§ 271.225 RRP implementation plan.

(a) An RRP plan shall describe how the railroad will implement its RRP. A railroad may implement its RRP in stages, so long as the railroad fully implements the entire RRP within 36 months of FRA's approval of the plan.

(b) At a minimum, a railroad's implementation plan shall:

(1) Cover the entire implementation period;

(2) Contain a timeline describing when certain implementation milestones will be achieved. Implementation milestones shall be specific and measurable;

(3) Describe the roles and responsibilities of each position or job function that has significant responsibility for implementing the railroad's RRP or any changes to the railroad's RRP (including any such positions or job functions held by a person that enters into a contractual relationship with the railroad to either perform significant safety-related services on the railroad's behalf or to utilize significant safety-related services provided by the railroad for railroad operations purposes); and

(4) Describe how significant changes to the RRP may be made.

Subpart D—Review, Approval, and Retention of Risk Reduction Program Plans

§ 271.301 Filing and approval.

(a) *Filing.* A railroad shall submit one copy of its RRP plan to the FRA Associate Administrator for Railroad Safety and Chief Safety Officer, 1200 New Jersey Avenue SE, Washington, DC 20590.

(b) *Filing timeline.* (1) A Class I railroad shall submit its RRP plan no later than August 16, 2021.

(2) A railroad with inadequate safety performance shall submit its RRP plan no later than 180 days after receiving final written notification from FRA that it shall comply with this part, pursuant to § 271.13(d), or no later than August 16, 2021, whichever is later.

(3) A railroad that the STB reclassifies or newly classifies as a Class I railroad shall submit its RRP plan no later than 90 days following the effective date of the classification or reclassification or no later than August 16, 2021, whichever is later.

(4)(i) Before submitting an RRP plan for FRA's review and approval, a voluntarily-compliant railroad shall notify FRA of its intent to submit an RRP plan by providing written notice to the FRA Associate Administrator for Railroad Safety and Chief Safety Officer, 1200 New Jersey Avenue SE, Washington, DC 20590.

(ii) The date that FRA receives a voluntarily-compliant railroad's written notice or February 18, 2021, whichever is later, serves as the date on which the voluntarily-compliant railroad may start compiling or collecting information solely for the purpose of planning, implementing, or evaluating a risk reduction program, as described by § 271.11.

(iii) A voluntarily-compliant railroad shall submit its RRP plan no later than 180 days after FRA receives written notice that the voluntarily-compliant railroad intends to submit an RRP plan for review and approval.

(c) *RRP plan requirements.* An RRP plan submitted by a railroad shall include:

(1) The signature, name, title, address, and telephone number of the chief official responsible for safety and who bears the primary managerial authority for implementing the submitting railroad's safety policy. By signing, this chief official is certifying that the contents of the RRP plan are accurate and that the railroad will implement the contents of the program as approved by FRA;

(2) The contact information for the primary person responsible for managing the RRP;

(3) The contact information for the senior representatives of any person that the railroad has determined has entered into a contractual relationship with the railroad to either perform significant safety-related services on the railroad's

behalf or to utilize significant safety-related services provided by the railroad for railroad operations purposes (including host railroads, contract operators, shared track/corridor operators, and other contractors); and

(4) As required by § 271.207(d), a statement describing how it consulted with its directly affected employees on the contents of its RRP plan. Directly affected employees have 30 days following the railroad's submission of its proposed RRP plan to file a statement under § 271.207(e)(2).

(d) *Approval.* (1) Within 90 days of receipt of an RRP plan, or within 90 days of receipt of each RRP plan submitted before the start of railroad operations, FRA will review the proposed RRP plan to determine if it sufficiently addresses the required elements. This review will also consider any statement submitted by directly affected employees pursuant to § 271.207(e).

(2) FRA will notify the primary contact person of the submitting railroad in writing whether FRA has approved the proposed plan and, if not approved, the specific points in which the RRP plan is deficient. FRA will also provide this notification to each individual identified in the service list accompanying the consultation statement required under § 271.207(d).

(3) If FRA does not approve an RRP plan, the submitting railroad shall amend the proposed plan to correct all identified deficiencies and shall provide FRA a corrected copy no later than 90 days following receipt of FRA's written notice that the submitted plan was not approved. If FRA determines that the necessary corrections are substantively significant, it will direct the railroad to consult further with its directly affected employees regarding the corrections. If the corrections are substantively significant, a railroad will also be required to include an updated consultation statement, along with its resubmitted plan, pursuant to § 271.207(d). Directly affected employees will also have 30 days following the railroad's resubmission of its proposed RRP plan to file a statement addressing the substantively significant changes under § 271.207(e). Within 60 days of receipt of a corrected RRP plan, FRA will review the corrected RRP plan to determine if it sufficiently addresses the identified deficiencies.

(4) Approval of a railroad's RRP plan under this part does not constitute approval of the specific actions the railroad will implement under its RRP plan and shall not be construed as establishing a Federal standard regarding those specific actions.

(e) *Electronic submission.* All documents required to be submitted to FRA under this part may be submitted electronically pursuant to the procedures in appendix B to this part.

§ 271.303 Amendments.

(a) *Consultation requirements.* (1) For substantive amendments, a railroad shall follow the process, described in its RRP plan pursuant to § 271.209, for consulting with its directly affected employees and submitting a consultation statement to FRA. The requirements of this paragraph (a)(1) do not apply to non-substantive amendments (*e.g.,* amendments that update names and addresses of railroad personnel).

(2) If a railroad and its directly affected employees cannot reach agreement on the proposed contents of a substantive amendment, the directly affected employees may file a statement with FRA under the procedures in § 271.207(e)(1). A railroad's directly affected employees have 15 days following the railroad's submission of a proposed amendment to submit the statement described in this paragraph.

(b) *Filing.* (1) A railroad shall submit any amendment(s) to its approved RRP plan to FRA's Associate Administrator not less than 60 days before the proposed effective date of the amendment(s). The railroad shall file the amendment(s) with a cover letter outlining the proposed change(s) to the approved RRP plan.

(2) If the proposed amendment is limited to adding or changing a name, title, address, or telephone number of a person, FRA approval is not required under the process of this section, although the railroad shall still file the amended RRP plan with FRA's Associate Administrator for Railroad Safety and Chief Safety Officer. These proposed amendments may be implemented by the railroad upon filing with FRA. All other proposed amendments must comply with the formal approval process described by this section.

(c) *Review.* (1) FRA will review a proposed amendment to an RRP plan within 45 days of receipt. FRA will then notify the primary contact person of the railroad regarding whether FRA has approved the proposed amendment. FRA will also provide this notification to each individual identified in the service list accompanying the consultation statement required under paragraph (a)(1) of this section. If not approved, FRA will inform the railroad and the individuals identified in the service list of the specific points in which the proposed amendment is deficient.

(2) If FRA has not notified the railroad and the individuals identified in the service list by the proposed effective date of the amendment whether the amendment has been approved or not, the railroad may implement the amendment, subject to FRA's decision.

(3) If a proposed RRP plan amendment is not approved by FRA, no later than 60 days following the receipt of FRA's written notice, the railroad shall either provide FRA a corrected copy of the amendment that addresses all deficiencies noted by FRA or notice that the railroad is retracting the amendment.

§ 271.305 Reopened review.

Following approval of an RRP plan or an amendment to such a plan, FRA may reopen review of the plan or amendment, in whole or in part, for cause stated.

§ 271.307 Retention of RRP plans.

(a) *Railroads.* A railroad shall retain at its system and division headquarters one copy of its RRP plan and each subsequent amendment to that plan. A railroad may comply with this requirement by making an electronic copy available.

(b) *Inspection and copying.* A railroad shall make a copy of the RRP plan and each subsequent amendment available to representatives of FRA or States participating under part 212 of this chapter for inspection and copying during normal business hours.

Subpart E—Internal Assessments

§ 271.401 Annual internal assessments.

(a) Beginning with the first calendar year after the calendar year in which FRA approves a railroad's RRP plan pursuant to § 271.301(d), the railroad shall annually (*i.e.,* once every calendar year) conduct an internal assessment of its RRP.

(b) The internal assessment shall determine the extent to which the railroad has:

(1) Achieved the implementation milestones described in its RRP plan pursuant to § 271.225(b);

(2) Complied with the implemented elements of the approved RRP plan;

(3) Achieved the goals described in its RRP plan pursuant to § 271.203(c);

(4) Implemented previous internal assessment improvement plans pursuant to § 271.403; and

(5) Implemented previous external audit improvement plans pursuant to § 271.503.

(c) A railroad shall ensure that the results of its internal assessments are

internally reported to railroad senior management.

§ 271.403 Internal assessment improvement plans.

(a) Within 30 days of completing its internal assessment, a railroad shall develop an improvement plan that addresses the findings of its internal assessment.

(b) At a minimum, a railroad's improvement plan shall:

(1) Describe recommended improvements (including any proposed revisions or updates to the RRP plan the railroad expects to make through the amendment process described in § 271.303) that address the findings of the internal assessment for fully implementing the railroad's RRP, complying with the implemented elements of the RRP plan, achieving the goals identified in the railroad's RRP plan pursuant to § 271.203(c), and implementing previous internal assessment improvement plans and external audit improvement plans;

(2) Identify by position title the individual who is responsible for carrying out the recommended improvements;

(3) Contain a timeline describing when specific and measurable milestones for implementing the recommended improvements will be achieved; and

(4) Specify processes for monitoring the implementation and evaluating the effectiveness of the recommended improvements.

§ 271.405 Internal assessment reports.

(a) Within 60 days of completing its internal assessment, a railroad shall submit a copy of an internal assessment report to the FRA Associate Administrator for Railroad Safety and Chief Safety Officer, 1200 New Jersey Avenue SE, Washington, DC 20590.

(b) This report shall be signed by the railroad's chief official responsible for safety and who bears primary managerial authority for implementing the railroad's safety policy. The report shall include:

(1) A description of the railroad's internal assessment;

(2) The findings of the internal assessment;

(3) A specific description of the recommended improvements contained in the railroad's internal assessment improvement plan, including any proposed amendments the railroad intends to make to the railroad's RRP plan pursuant to § 271.303; and

(4) The status of the recommended improvements contained in the railroad's internal assessment improvement plan and any outstanding recommended improvements from previous internal assessment improvement plans.

Subpart F—External Audits

§ 271.501 External audits.

FRA will conduct (or cause to be conducted) external audits of a railroad's RRP. Each audit shall evaluate the railroad's compliance with the elements of its RRP required by this part. A railroad shall make documentation kept pursuant to its RRP plan available for inspection and copying by representatives of FRA or States participating under part 212 of this chapter upon request. FRA will provide a railroad written notice of the audit results.

§ 271.503 External audit improvement plans.

(a) *Submission.* Within 60 days of receiving FRA's written notice of the audit results, if necessary, a railroad shall submit for approval an improvement plan addressing any instances of deficiency or non-compliance found in the audit to the FRA Associate Administrator for Railroad Safety and Chief Safety Officer, 1200 New Jersey Avenue SE, Washington, DC 20590.

(b) *Requirements.* At a minimum, an improvement plan shall:

(1) Describe the improvements the railroad will implement to address the audit findings;

(2) Identify by position title the individual(s) responsible for carrying out the improvements necessary to address the audit findings; and

(3) Contain a timeline describing when milestones for implementing the recommended improvements will be achieved. These implementation milestones shall be specific and measurable.

(c) *Approval.* If FRA does not approve the railroad's improvement plan, FRA will notify the railroad of the plan's specific deficiencies. The railroad shall amend the proposed plan to correct the identified deficiencies and provide FRA a corrected copy no later than 30 days following receipt of FRA's notice that the proposed plan was not approved.

(d) *Status reports.* Upon the request of the FRA Associate Administrator, a railroad shall provide FRA for review a status report on the implementation of the improvements contained in the improvement plan.

Appendix A to Part 271—Federal Railroad Administration Guidance on the Risk Reduction Program Consultation Process

A railroad required to develop a risk reduction program (RRP) under this part shall in good faith consult with and use its best efforts to reach agreement with its directly affected employees on the contents of the RRP plan. *See* § 271.207(a)(1). This appendix discusses the meaning of the terms ''good faith'' and ''best efforts,'' and provides non-mandatory guidance on how a railroad may comply with the requirement to consult with directly affected employees on the contents of its RRP plan. Guidance is provided for employees who are represented by a non-profit employee labor organization and employees who are not represented by any such organization.

I. The Meaning of ''Good Faith'' and ''Best Efforts''

''Good faith'' and ''best efforts'' are not interchangeable terms representing a vague standard for the § 271.207 consultation process. Rather, each term has a specific and distinct meaning. When consulting with directly affected employees, therefore, a railroad shall independently meet the standards for both the good faith and best efforts obligations. A railroad that does not meet the standard for one or the other will not be in compliance with the consultation requirements of § 271.207.

The good faith obligation requires a railroad to consult with employees in a manner that is honest, fair, and reasonable, and to genuinely pursue agreement on the contents of an RRP plan. If a railroad consults with its employees merely in a perfunctory manner, without genuinely pursuing agreement, it will not have met the good faith requirement. For example, a lack of good faith may be found if a railroad's directly affected employees express concerns with certain parts of the railroad's RRP plan, and the railroad neither addresses those concerns in further consultation nor attempts to address those concerns by making changes to the RRP plan.

On the other hand, ''best efforts'' establishes a higher standard than that imposed by the good faith obligation, and describes the diligent attempts that a railroad shall pursue to reach agreement with its employees on the contents of its RRP plan. While the good faith obligation is concerned with the railroad's state of mind during the consultation process, the best efforts obligation is concerned with the specific efforts made by the railroad in an attempt to reach agreement. This would include considerations such as whether a railroad had held sufficient meetings with its employees to address or make an attempt to address any concerns raised by the employees, or whether the railroad had made an effort to respond to feedback provided by employees during the consultation process. For example, a railroad would not meet the best efforts obligation if it did not initiate the consultation process in a timely manner, and thereby failed to provide employees sufficient time to engage in the consultation

process. A railroad would also likely not meet the best efforts obligation if it presented employees with an RRP plan and only permitted the employees to express agreement or disagreement on the plan (assuming that the employees had not previously indicated that such a consultation would be acceptable). A railroad may, however, wish to hold off substantive consultations regarding the contents of its RRP plan until one year after publication of the rule to ensure that information generated as part of the process is protected from discovery and admissibility into evidence under § 271.11. Generally, best efforts are measured by the measures that a reasonable person in the same circumstances and of the same nature as the acting party would take. Therefore, the standard imposed by the best efforts obligation may vary with different railroads, depending on a railroad's size, resources, and number of employees.

When reviewing RRP plans, FRA will determine on a case-by-case basis whether a railroad has met its § 271.207 good faith and best efforts obligations. This determination will be based upon the consultation statement submitted by the railroad pursuant to § 271.207(b) and any statements submitted by employees pursuant to § 271.207(c). If FRA finds that these statements do not provide sufficient information to determine whether a railroad used good faith and best efforts to reach agreement, FRA may investigate further and contact the railroad or its employees to request additional information. (FRA also expects a railroad's directly affected employees to utilize good faith and best efforts when negotiating on the contents of an RRP plan. If FRA's review and investigation of the statements submitted by the railroad under § 271.207(b) and the directly affected employees under § 271.207(c) reveal that the directly affected employees did not utilize good faith and best efforts, FRA could consider this as part of its approval process.)

If FRA determines that a railroad did not use good faith and best efforts, FRA may disapprove the RRP plan submitted by the railroad and direct the railroad to comply with the consultation requirements of § 271.207. Pursuant to § 271.301(b)(3), if FRA does not approve the RRP plan, the railroad will have 90 days, following receipt of FRA's written notice that the plan was not approved, to correct any deficiency identified. In such cases, the identified deficiency would be that the railroad did not use good faith and best efforts to consult and reach agreement with its directly affected employees. If a railroad then does not submit to FRA within 90 days an RRP plan meeting the consultation requirements of § 271.207, the railroad could be subject to penalties for failure to comply with § 271.301(b)(3).

II. Guidance on How a Railroad May Consult With Directly Affected Employees

Because the standard imposed by the best efforts obligation will vary depending upon the railroad, there may be countless ways for various railroads to comply with the consultation requirements of § 271.207. Therefore, it is important to maintain a flexible approach to the § 271.207 consultation requirements, to give a railroad and its directly affected employees the freedom to consult in a manner best suited to their specific circumstances.

FRA is nevertheless providing guidance in this appendix as to how a railroad may proceed when consulting (utilizing good faith and best efforts) with employees in an attempt to reach agreement on the contents of an RRP plan. This guidance may be useful as a starting point for railroads that are uncertain about how to comply with the § 271.207 consultation requirements. This guidance distinguishes between employees who are represented by a non-profit employee labor organization and employees who are not, as the processes a railroad may use to consult with represented and non-represented employees could differ significantly.

This guidance does not establish prescriptive requirements with which a railroad shall comply, but merely outlines a consultation process a railroad may choose to follow. A railroad's consultation statement could indicate that the railroad followed the guidance in this appendix as evidence that it utilized good faith and best efforts to reach agreement with its employees on the contents of an RRP plan.

(a) Employees Represented by a Non-Profit Employee Labor Organization

As provided in § 271.207(b)(1), a railroad consulting with the representatives of a non-profit employee labor organization on the contents of an RRP plan will be considered to have consulted with the directly affected employees represented by that organization.

A railroad may utilize the following process as a roadmap for using good faith and best efforts when consulting with represented employees in an attempt to reach agreement on the contents of an RRP plan.

(1) Pursuant to § 271.207(b)(1), a railroad must meet with representatives from a non-profit employee labor organization (representing a class or craft of the railroad's directly affected employees) within 240 days from February 18, 2020 to begin the process of consulting on the contents of the railroad's RRP plan. A railroad must provide notice at least 60 days before the scheduled meeting.

(2) During the time between the initial meeting and the applicability date of § 271.11, the parties may meet to discuss administrative details of the consultation process as necessary.

(3) Within 60 days after February 17, 2021, a railroad should have a meeting with the representatives of the directly affected employees to discuss substantive issues with the RRP plan.

(4) Within 180 days after February 17, 2021 or as otherwise provided by § 271.301(b), a railroad would file its RRP plan with FRA.

(5) As provided by § 271.207(e), if agreement on the contents of an RRP plan could not be reached, a labor organization (representing a class or craft of the railroad's directly affected employees) may file a statement with the FRA Associate Administrator for Railroad Safety and Chief Safety Officer explaining its views on the plan on which agreement was not reached.

(b) Employees Who Are Not Represented by a Non-Profit Employee Labor Organization

FRA recognizes that some (or all) of a railroad's directly affected employees may not be represented by a non-profit employee labor organization. For such non-represented employees, the consultation process described for represented employees may not be appropriate or sufficient. For example, a railroad with non-represented employees should make a concerted effort to ensure that its non-represented employees are aware that they are able to participate in the development of the railroad's RRP plan. FRA therefore is providing the following guidance regarding how a railroad may utilize good faith and best efforts when consulting with non-represented employees on the contents of its RRP plan.

(1) Within 120 days from February 18, 2020, a railroad may notify non-represented employees that—

(A) The railroad is required to consult in good faith with, and use its best efforts to reach agreement with, all directly affected employees on the proposed contents of its RRP plan;

(B) Non-represented employees are invited to participate in the consultation process (and include instructions on how to engage in this process); and

(C) If a railroad is unable to reach agreement with its directly affected employees on the contents of the proposed RRP plan, an employee may file a statement with the FRA Associate Administrator for Railroad Safety and Chief Safety Officer explaining his or her views on the plan on which agreement was not reached.

(2) This initial notification (and all subsequent communications, as necessary or appropriate) could be provided to non-represented employees in the following ways:

(A) Electronically, such as by email or an announcement on the railroad's website;

(B) By posting the notification in a location easily accessible and visible to non-represented employees; or

(C) By providing all non-represented employees a hard copy of the notification.

A railroad could use any or all of these methods of communication, so long as the notification complies with the railroad's obligation to utilize best efforts in the consultation process.

(3) Following the initial notification (and before submitting its RRP plan to FRA), a railroad should provide non-represented employees a draft proposal of its RRP plan. This draft proposal should solicit additional input from non-represented employees, and the railroad should provide non-represented employees 60 days to submit comments to the railroad on the draft.

(4) Following this 60-day comment period and any changes to the draft RRP plan made as a result, the railroad should submit the proposed RRP plan to FRA, as required by this part.

(5) As provided by § 271.207(e), if agreement on the contents of an RRP plan cannot be reached, then a non-represented employee may file a statement with the FRA Associate Administrator for Railroad Safety and Chief Safety Officer explaining his or her

views on the plan on which agreement was not reached.

Appendix B to Part 271—Procedures for Submission of RRP Plans and Statements From Directly Affected Employees

This appendix establishes procedures for the submission of a railroad's RRP plan and statements by directly affected employees consistent with the requirements of this part.

Submission by a Railroad and Directly Affected Employees

(a) As provided for in § 271.101, each railroad must establish and fully implement an RRP that continually and systematically evaluates railroad safety hazards on its system and manages the resulting risks to reduce the number and rates of railroad accidents, incidents, injuries, and fatalities. The RRP shall be fully implemented and supported by a written RRP plan. Each railroad must submit its RRP plan to FRA for approval as provided for in § 271.201.

(b) As provided for in § 271.207(e), if a railroad and its directly affected employees cannot come to agreement on the proposed contents of the railroad's RRP plan, the directly affected employees have 30 days following the railroad's submission of its proposed RRP plan to submit a statement to the FRA Associate Administrator for Railroad Safety and Chief Safety Officer explaining the directly affected employees' views on the plan on which agreement was not reached.

(c) The railroad's and directly affected employees' submissions shall be sent to the Associate Administrator for Railroad Safety and Chief Safety Officer, FRA. The mailing address for FRA is 1200 New Jersey Avenue SE, Washington, DC 20590. When a railroad submits its RRP plan and consultation statement to FRA pursuant to § 271.301, it must also simultaneously send a copy of these documents to all individuals identified in the service list pursuant to § 271.207(d)(3).

(d) Each railroad and directly affected employee is authorized to file by electronic means any submissions required under this part. Before any person files a submission electronically, the person shall provide the FRA Associate Administrator for Railroad Safety and Chief Safety Officer with the following information in writing:

(1) The name of the railroad or directly affected employee(s);

(2) The names of two individuals, including job titles, who will be the railroad's or directly affected employees' points of contact and will be the only individuals allowed access to FRA's secure document submission site;

(3) The mailing addresses for the railroad's or directly affected employees' points of contact;

(4) The railroad's system or main headquarters address located in the United States;

(5) The email addresses for the railroad's or directly affected employees' points of contact; and

(6) The daytime telephone numbers for the railroad's or directly affected employees' points of contact.

(e) A request for electronic submission or FRA review of written materials shall be addressed to the FRA Associate Administrator for Railroad Safety and Chief Safety Officer, Federal Railroad Administration, 1200 New Jersey Avenue SE, Washington, DC 20590. Upon receipt of a request for electronic submission that contains the information listed above, FRA will then contact the requestor with instructions for electronically submitting its program or statement. A railroad that electronically submits an initial RRP plan or new portions or revisions to an approved program required by this part shall be considered to have provided its consent to receive approval or disapproval notices from FRA by email. FRA may electronically store any materials required by this part regardless of whether the railroad that submits the materials does so by delivering the written materials to the Associate Administrator and opts not to submit the materials electronically. A railroad that opts not to submit the materials required by this part electronically, but provides one or more email addresses in its submission, shall be considered to have provided its consent to receive approval or disapproval notices from FRA by email or mail.

Issued in Washington, DC.

Ronald L. Batory,

Administrator, Federal Railroad Administration.

[FR Doc. 2020–00425 Filed 2–14–20; 8:45 am]

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Part IV

Nuclear Regulatory Commission

10 CFR Parts 170 and 171

Revision of Fee Schedules; Fee Recovery for Fiscal Year 2020; Proposed Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 170 and 171

[NRC–2017–0228; Docket No. PRM–171–1; NRC–2019–0084]

RIN 3150–AK10

Revision of Fee Schedules; Fee Recovery for Fiscal Year 2020

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend the licensing, inspection, special project, and annual fees charged to its applicants and licensees. These proposed amendments are necessary to implement the Omnibus Budget Reconciliation Act of 1990, as amended (OBRA–90), which requires the NRC to recover approximately 90 percent of its annual budget through fees less certain amounts excluded from this fee-recovery requirement.

DATES: Submit comments by March 19, 2020. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received before this date. Because OBRA–90 requires the NRC to collect the FY 2020 fees by September 30, 2020, the NRC must finalize any revisions to its fee schedules promptly, and thus be unable to grant any request for an extension of the comment period.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2017–0228. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule.
- *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301–415–1677.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Anthony Rossi, Office of the Chief Financial Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–7341; email: *Anthony.Rossi@nrc.gov.*

SUPPLEMENTARY INFORMATION:

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2017–0228 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2017–0228.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209 or 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced. For the convenience of the reader, the ADAMS accession numbers are also provided in a table in the ''Availability of Documents'' section of this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2017–0228 in the subject line of your comment submission in order to ensure that the NRC is able to make your comment submission publicly available in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at *https://www.regulations.gov* as well as entering the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submissions. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Background; Statutory Authority

The NRC's fee regulations are primarily governed by two laws: (1) The Independent Offices Appropriation Act, 1952 (IOAA) (31 U.S.C. 9701), and (2) OBRA–90 (42 U.S.C. 2214). The IOAA generally authorizes and encourages Federal regulatory agencies to recover—to the fullest extent possible—costs attributable to services provided to identifiable recipients. Under OBRA–90, the NRC must recover approximately 90 percent of its budget authority for the fiscal year through fees. In FY 2020, the following appropriated amounts are excluded from the fee-recovery requirement: The development of a regulatory infrastructure for advanced nuclear reactor technologies, international activities, generic homeland security activities, Waste Incidental to Reprocessing, and Inspector General services for the Defense Nuclear Facilities Safety Board. Under OBRA–90, the NRC must use its IOAA authority first to collect service fees for NRC work that provides specific benefits to identifiable applicants and licensees (such as licensing work, inspections, and special projects).

The NRC's regulations in part 170 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as amended,'' authorize the fees the agency is required to collect from specific beneficiaries. But, because the NRC's fee recovery under the IOAA (10 CFR part 170) will not equal 90 percent of the agency's budget authority for the fiscal year, the NRC also assesses ''annual fees'' under 10 CFR part 171, ''Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC,'' to recover the remaining amount necessary to meet OBRA–90's fee-recovery requirement.

III. Petition for Rulemaking: (PRM–171–1; NRC–2019–0084)

On February 28, 2019, the NRC received a petition for rulemaking (ADAMS Accession No. ML19081A015) from Dr. Michael D. Meier, on behalf of the Southern Nuclear Operating Company (the petitioner). The petitioner requested that the NRC revise its regulations in 10 CFR part 171 related to the start of the assessment of annual fees for combined license (COL) holders licensed under 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants,'' to align with the commencement of ''commercial operation,'' of a licensed nuclear power plant. Specifically, the petitioner requested that the NRC revise the timing of when annual fees commence for COL holders to coincide when a reactor achieves ''commercial operation,'' rather than when the NRC finds (under § 52.103(g)) that the acceptance criteria in the COL are met, after which the licensee can operate the facility. The NRC regulations at § 171.15 currently require a 10 CFR part 52 COL holder to pay the annual fee upon the Commission's finding under § 52.103(g). The NRC published a notice of docketing in the **Federal Register** (84 FR 26774; June 10, 2019), and requested public comment on the issues raised in PRM–171–1.

The NRC received five public comment submissions, containing seven comments, during the 30-day public comment period, from the Nuclear Energy Institute (NEI), several industry stakeholders, and one non-government organization. All comments supported the petitioner's request raised in the PRM. The petitioner requested the NRC consider this rule change within the context of its annual fee rulemaking to amend 10 CFR parts 170 and 171 to collect FY 2020 fees. The NRC published a notice in the **Federal Register** (84 FR 65032; November 26, 2019) that granted partial consideration by modifying the timing regarding the assessment of annual fees for 10 CFR part 52 COL holders in the FY 2020 proposed fee rule. In addition, two of the seven comments requested that the NRC expand the scope of any rulemaking associated with the PRM to include certain licensees under 10 CFR part 50. All responses to comments received on the petition will be addressed in the final fee rule.

Based on its review of PRM–171–1 and the public comments, the NRC is proposing to amend § 171.15(a) to modify the timing regarding the assessment of annual fees for 10 CFR part 52 COL holders. In addition, the NRC is proposing to amend the timing regarding the assessment of annual fees to apply to future 10 CFR part 50 power reactor licensees. See the FY 2020 Policy Changes section of this proposed rule for additional information on the proposed amendment resulting from PRM–171–1.

IV. Discussion

FY 2020 Fee Collection—Overview

The NRC is issuing this FY 2020 proposed fee rule based on Public Law (Pub. L.) 116–93—Further Consolidated Appropriations Act, 2020, (the enacted budget). The proposed fee rule reflects a budget authority in the amount of $855.6 million, a decrease of $55.4 million from FY 2019. As explained previously, certain portions of the NRC's total budget are excluded from OBRA–90's fee-recovery requirement. Based on the FY 2020 enacted budget, these exclusions total $46.6 million, consisting of $15.5 million for the development of a regulatory infrastructure for advanced nuclear reactor technologies; $14.5 million for international activities; $14.1 million for generic homeland security activities; $1.3 million for Waste Incidental to Reprocessing activities; and $1.2 million for Inspector General services for the Defense Nuclear Facilities Safety Board. Additionally, OBRA–90 requires the NRC to recover only approximately 90 percent of the remaining budget authority for the fiscal year—10 percent of the remaining budget authority need not be recovered through fees. The NRC refers to the activities included in this 10-percent as ''fee-relief'' activities.

After accounting for the fee-recovery exclusions, the fee-relief activities, and net billing adjustments (*i.e.,* the sum of unpaid current year invoices (estimated) minus payments for prior year invoices, and current year collections made for the termination of one operating power reactor), the NRC must recover approximately $728.5 million in fees in FY 2020. Of this amount, the NRC estimates that $230.6 million will be recovered through 10 CFR part 170 service fees and approximately $497.9 million will recovered through 10 CFR part 171 annual fees. Table I summarizes the fee-recovery amounts for the FY 2020 proposed fee rule using the enacted budget, and taking into account excluded activities, fee-relief activities, and net billing adjustments. For all information presented in the following tables, individual values may not sum to totals due to rounding. Please see the work papers (ADAMS Accession No. ML19343A735) for actual amounts.

Public Law 116–93—Further Consolidated Appropriations Act, 2020, also includes direction for the NRC to use $40.0 million in prior year unobligated carryover funds. The use of carryover funds allows the NRC to accomplish the work needed without additional costs to licensees because, consistent with the requirements of OBRA–90, fees are calculated based on the budget authority enacted for the current fiscal year and not carryover funds.

TABLE I—BUDGET AND FEE RECOVERY AMOUNTS [1]

[Dollars in millions]

	FY 2019 final rule	FY 2020 proposed rule	Percentage change
Total Budget Authority	$911.0	$855.6	−6.1
Less Excluded Fee Items	−43.4	−46.6	7.4
Balance	867.6	808.9	−6.8
Fee Recovery Percent	90	90	0.0
Total Amount to be Recovered:	780.8	728.1	−6.8
10 CFR Part 171 Billing Adjustments:			
Unpaid Current Year Invoices (estimated)	4.5	4.5	0.0
Less Current Year Collections from a Terminated Reactor—Indian Point Nuclear Generating, Unit 2	0.0	−2.4	100.00
Less Payments Received in Current Year for Previous Year Invoices (estimated)	−2.8	−1.7	−39.3
Subtotal	1.7	0.4	−76.5
Amount to be Recovered through 10 CFR Parts 170 and 171 Fees	782.5	728.5	−6.9
Less Estimated 10 CFR Part 170 Fees	−252.1	−230.6	−8.5
10 CFR Part 171 Fee Collections Required	$530.5	$497.9	−6.2

FY 2020 Fee Collection—Professional Hourly Rate

The NRC uses a professional hourly rate to assess fees under 10 CFR part 170 for specific services it provides. The professional hourly rate also helps determine flat fees (which are used for the review of certain types of license applications). This rate would be applicable to all activities for which fees are assessed under §§ 170.21 and 170.31.

The NRC's professional hourly rate is derived by adding budgeted resources for: (1) Mission-direct program salaries and benefits, (2) mission-indirect program support, and (3) agency support (corporate support and the Inspector General). The NRC then subtracts certain offsetting receipts and divides this total by the mission-direct full-time equivalents (FTE) converted to hours (the mission-direct FTE converted to hours is the product of the mission-direct FTE multiplied by the estimated annual mission-direct FTE productive hours). The only budgeted resources excluded from the professional hourly rate are those for mission-direct contract resources, which are generally billed to licensees separately. The following shows the professional hourly rate calculation:

$$\text{Professional Hourly Rate} = \frac{\text{Budgeted Resources}}{\text{Mission-Direct FTE Converted to Hours}} = \frac{\$716.9 \text{ million}}{1{,}701 \times 1{,}510} = \$279$$

For FY 2020, the NRC is proposing to increase the professional hourly rate from $275 to $279. The 0.4 percent increase in the FY 2020 professional hourly rate is due primarily to the anticipated decline in the number of mission-direct FTE compared to FY 2019. The number of mission-direct FTE is expected to decline by 109, primarily due to (1) the anticipated completion of the NuScale small modular reactor (SMR) design certification review; (2) a reduction in workload associated with the Clinch River Nuclear Site (Clinch River) early site permit; (3) the power reactor plant closures of Oyster Creek Nuclear Generating Station (Oyster Creek), Pilgrim Nuclear Power Station (Pilgrim), Three Mile Island Nuclear Generating Station, Unit 1 (TMI 1); and (4) the expected decline in submissions for fuel facility license renewal applications, the decrease in the number of license amendments, the termination of the Mixed-Oxide (MOX) Fuel Fabrication Facility construction authorization, and efficiencies gained within the fuel facilities inspection program. The FY 2020 estimate for annual mission-direct FTE productive hours is 1,510 hours, which is unchanged from FY 2019. This estimate, also referred to as the productive hours assumption, reflects the average number of hours that a mission-direct employee spends on mission-direct work in a given year. This estimate therefore excludes hours charged to annual leave, sick leave, holidays, training, and general administrative tasks. Table II shows the professional hourly rate calculation methodology. The FY 2019 amounts are provided for comparison purposes.

[1] For each table, numbers may not add due to rounding.

[2] The fees collected by the NRC for Freedom of Information Act (FOIA) services and indemnity fees (financial protection required of all licensees for public liability claims at 10 CFR part 140) are subtracted from the budgeted resources amount when calculating the 10 CFR part 170 professional hourly rate, per the guidance in the Office of Management and Budget (OMB) Circular A–25, *User Charges.* The budgeted resources for FOIA activities are allocated under the product for Information Services within the Corporate Support business line. The budgeted resources for indemnity activities are allocated under the Licensing Actions and Research and Test Reactors products within the Operating Reactors business line.

TABLE II—PROFESSIONAL HOURLY RATE CALCULATION

[Dollars in millions, except as noted]

	FY 2019 final rule	FY 2020 proposed rule	Percentage change
Mission-Direct Program Salaries & Benefits	$334.7	$314.6	−6.0
Mission-Indirect Program Support	$120.6	$110.8	−8.1
Agency Support (Corporate Support and the IG)	$304.5	$291.5	−4.3
Subtotal	$759.8	$716.9	−5.6
Less Offsetting Receipts [2]	$0.0	$0.0	0.0
Total Budgeted Resources Included in Professional Hourly Rate	$759.8	$716.9	−5.6
Mission-Direct FTE (Whole numbers)	1,810	1,701	−6.0
Annual Mission-Direct FTE Productive Hours (Whole numbers)	1,510	1,510	0.0
Mission-Direct FTE Converted to Hours (Mission-Direct FTE multiplied by Annual Mission-Direct FTE Productive Hours) (In Millions)	2,733,100	2,568,510	−6.0
Professional Hourly Rate (Total Budgeted Resources Included in Professional Hourly Rate Divided by Mission-Direct FTE Converted to Hours) (Whole Numbers)	$278	$279	0.4

FY 2020 Fee Collection—Flat Application Fee Changes

The NRC proposes to amend the flat application fees that it charges in its schedule of fees in §§ 170.21 and 170.31 to reflect the revised professional hourly rate of $279. The NRC charges these fees to applicants for materials licenses and other regulatory services, as well as holders of materials licenses. The NRC calculates these flat fees by multiplying the average professional staff hours needed to process the licensing actions by the proposed professional hourly rate for FY 2020. As part of its calculations, the NRC analyzes the actual hours spent performing licensing actions and estimates the five-year average professional staff hours that are needed to process licensing actions as part of its biennial review of fees, which is required by Section 205(a) of the Chief Financial Officers Act of 1990 (31 U.S.C. 902(a)(8)). The NRC performed this review in FY 2019 and will perform this review again in FY 2021. The higher professional hourly rate of $279 is the primary reason for the increase in application fees. Please see the work papers for more detail.

The NRC rounds these flat fees in such a way that ensures both convenience for its stakeholders and that any rounding effects are minimal. Accordingly, fees under $1,000 are rounded to the nearest $10, fees between $1,000 and $100,000 are rounded to the nearest $100, and fees greater than $100,000 are rounded to the nearest $1,000.

The proposed licensing flat fees are applicable for certain materials licensing actions (see fee categories 1.C. through 1.D., 2.B. through 2.F., 3.A. through 3.S., 4.B. through 5.A., 6.A. through 9.D., 10.B., 15.A. through 15.L., 15.R., and 16 of § 170.31). Because the enacted budget excludes international activities from the fee-recoverable budget, the NRC is not proposing to charge flat fees for import and export licensing actions described in § 170.21. Applications filed on or after the effective date of the FY 2020 final fee rule will be subject to the revised fees in the final rule.

FY 2020 Fee Collection—Fee-Relief and Low-Level Waste Surcharge

As previously noted, OBRA–90 requires the NRC to recover approximately 90 percent of its annual budget authority for the fiscal year. The NRC applies the remaining 10 percent that is not recovered to offset certain budgeted activities—see Table III for a full listing of these ''fee-relief'' activities. If the amount budgeted for these fee-relief activities is greater or less than 10 percent of the NRC's annual budget authority (less the fee-recovery exclusions), then the NRC applies a fee adjustment (either an increase or decrease) to all licensees' annual fees, based on the percentage of the NRC's budgeted resources allocated to each fee class.

In FY 2020, the amount budgeted for fee-relief activities is less than the 10 percent threshold. Therefore, the NRC proposes to assess a fee-relief credit that decreases all licensees' annual fees. Table III summarizes the fee-relief activities budgeted for FY 2020. The FY 2019 amounts are provided for comparison purposes.

TABLE III—FEE–RELIEF ACTIVITIES

[Dollars in millions]

Fee-relief activities	FY 2019 budgeted resources final rule	FY 2020 budgeted resources proposed rule	Percentage change
1. Activities not attributable to an existing NRC licensee or class of licensees:			
a. Agreement State oversight	$11.5	$11.9	3.8
b. Scholarships and Fellowships	15.0	16.0	6.7
c. Medical Isotope Production Infrastructure	5.4	2.7	−50.0
2. Activities not assessed under 10 CFR part 170 service fees or 10 CFR part 171 annual fees based on existing law or Commission policy:			
a. Fee exemption for nonprofit educational institutions	9.1	9.0	−1.1
b. Costs not recovered from small entities under 10 CFR 171.16(c)	8.0	7.6	−4.9
c. Regulatory support to Agreement States	14.7	12.2	−17.3

TABLE III—FEE–RELIEF ACTIVITIES—Continued

[Dollars in millions]

Fee-relief activities	FY 2019 budgeted resources final rule	FY 2020 budgeted resources proposed rule	Percentage change
d. Generic decommissioning/reclamation (not related to the power reactor and spent fuel storage fee classes)	12.9	12.0	−7.0
e. Uranium recovery program and unregistered general licensees	7.2	5.2	−27.8
f. Potential Department of Defense remediation program Memorandum of Understanding activities	2.1	1.7	−16.7
g. Non-military radium sites	1.1	0.8	−23.4
Total fee-relief activities	87.0	79.2	−9.0
Less 10 percent of the NRC's total FY budget (less the fee recovery exclusions)	−86.8	−80.9	−6.8
Fee-Relief Adjustment to be Allocated to All Licensees' Annual Fees	$0.3	−1.7	−673.0

Table IV shows how the NRC proposes to allocate the $1.7 million fee-relief credit to each licensee fee class. In addition to the fee-relief credit, the NRC proposes assessing a generic low-level waste (LLW) surcharge of $3.4 million. Disposal of LLW occurs at commercially operated LLW disposal facilities that are licensed by either the NRC or an Agreement State. Four existing LLW disposal facilities in the United States accept various types of LLW. All are located in Agreement States and, therefore, are regulated by an Agreement State, rather than the NRC. The NRC proposes to allocate this surcharge to its licensees based on data available in the U.S. Department of Energy's (DOE) Manifest Information Management System. This database contains information on total LLW volumes and NRC usage information from four generator classes: Academic, industrial, medical, and utility. The ratio of utility waste volumes to total LLW volumes over a period of time is used to estimate the portion of this surcharge that will be allocated to the power reactors, fuel facilities, and materials fee classes. The materials portion is adjusted to account for the fact that a large percentage of materials licensees are licensed by the Agreement States rather than the NRC.

Table IV shows the LLW surcharge and fee-relief credit, and its proposed allocation across the various fee classes.

TABLE IV—ALLOCATION OF FEE–RELIEF ADJUSTMENT AND LLW SURCHARGE FY 2020

[Dollars in millions]

	LLW surcharge		Fee-relief adjustment		Total
	Percent	$	Percent	$	$
Operating Power Reactors	84.0	2.881	86.4	−1.485	1.396
Spent Fuel Storage/Reactor Decommissioning	0.0	0.000	5.4	−0.092	−0.092
Research and Test Reactors	0.0	0.000	0.5	−0.009	−0.009
Fuel Facilities	12.7	0.436	3.4	−0.058	0.378
Materials Users	3.3	0.113	3.8	−0.065	0.048
Transportation	0.0	0.000	0.5	−0.009	−0.009
Rare Earth Facilities	0.0	0.000	0.0	0.0	0.0
Uranium Recovery	0.0	0.000	0.1	−0.001	−0.001
Total	100.0	3.430	100.0	−1.719	1.711

FY 2020 Fee Collection—Revised Annual Fees

In accordance with SECY–05–0164, ''Annual Fee Calculation Method'' (ADAMS Accession No. ML052580332), the NRC rebaselines its annual fees every year. ''Rebaselining'' entails analyzing the budget in detail and then allocating the budgeted costs to various classes or subclasses of licensees. It also includes updating the number of NRC licensees in its fee calculation methodology.

The NRC proposes to revise its annual fees in §§ 171.15 and 171.16 to recover approximately 90 percent of the NRC's FY 2020 enacted budget (less the fee-recovery exclusions and the estimated amount to be recovered through 10 CFR part 170 fees). The total estimated 10 CFR part 170 collections for this proposed rule are $230.6 million, a decrease of $21.5 million from the FY 2019 final rule (see the specific fee class sections for a discussion of this decrease). The NRC, therefore, proposes to recover $497.9 million through annual fees from its licensees, which is a decrease of $32.6 million from the FY 2019 final rule.

Table V shows the proposed rebaselined fees for FY 2020 for a representative list of licensee categories. The FY 2019 amounts are provided for comparison purposes.

TABLE V—REBASELINED ANNUAL FEES

[Actual dollars]

Class/category of licenses	FY 2019 final annual fee	FY 2020 proposed annual fee	Percentage change
Operating Power Reactors	$4,669,000	$4,534,000	−2.9
+ Spent Fuel Storage/Reactor Decommissioning	152,000	172,000	13.2
Total, Combined Fee	$4,821,000	$4,706,000	−2.4
Spent Fuel Storage/Reactor Decommissioning	152,000	172,000	13.2
Research and Test Reactors (Non-power Reactors)	82,400	79,200	−3.9
High Enriched Uranium Fuel Facility	$6,675,000	$4,944,000	−25.9
Low Enriched Uranium Fuel Facility	$2,262,000	$1,675,000	−26.0
UF_6 Conversion and Deconversion Facility	$1,417,000	$1,049,000	−26.0
Basic *In Situ* Recovery Facilities (Category 2.A.(2)(b))	$49,200	$49,200	0.0
Typical Users:			
Radiographers (Category 3O)	$30,200	$29,800	−1.3
All Other Specific Byproduct Material Licensees (Category 3P)	$10,000	$9,700	−3.0
Medical Other (Category 7C)	$15,300	$14,800	−3.3
Device/Product Safety Evaluation—Broad (Category 9A)	$14,300	$13,800	−3.5

The work papers that support this proposed rule show in detail how the NRC proposes to allocate the budgeted resources for each class of licensees and calculate the fees.

Paragraphs a. through h. of this section describe budgeted resources allocated to each class of licensees and the calculations of the rebaselined fees. For more information about detailed fee calculations for each class, please consult the accompanying work papers.

a. Operating Power Reactors

The NRC proposes to collect $430.7 million in annual fees from the operating power reactors fee class in FY 2020, as shown in Table VI. The FY 2019 fees and percentage changes are shown for comparison purposes.

TABLE VI—ANNUAL FEE SUMMARY CALCULATIONS FOR OPERATING POWER REACTORS

[Dollars in millions]

Summary fee calculations	FY 2019 final	FY 2020 proposed	Percentage change
Total budgeted resources	$670.2	$623.9	−6.9
Less estimated 10 CFR part 170 receipts	−217.7	−194.8	−10.5
Net 10 CFR part 171 resources	452.5	429.1	−5.2
Allocated generic transportation	0.2	0.2	1.3
Fee-relief adjustment/LLW surcharge	3.4	1.4	−59.1
Billing adjustment	1.5	2.4	64.5
Adjustment: Estimated current year collections from terminated reactor (Indian Point Nuclear Generating, Unit 2)	0.0	−2.4	100.0
Total required annual fee recovery	457.6	430.7	−5.9
Total operating reactors	98	95	−3.1
Annual fee per reactor	$4.669	$4.534	−2.9

In comparison to FY 2019, the resources budgeted for the operating power reactors fee class decreased by $46.3 million due to a decline in FTEs as a result of the following: (1) The closures of Oyster Creek, Pilgrim, and TMI 1; (2) the delay in receipt of the Utah Associated Municipal Power System SMR application; (3) withdrawal of the Blue Castle large light-water reactor application; (4) delay in the submittal of the Advanced Passive 1000 design certification renewal application; (5) the near completion of the NuScale SMR design certification review; (6) the completion of the Clinch River early site permit technical review; (7) a reduction in license amendment requests for the Vogtle Electric Generating Plant; (8) expected delays in construction and operating license application review activities for Bellefonte Nuclear Station, Units 1 and 2; (9) efficiencies gained from the merger of the Office of Nuclear Reactor Regulation and the Office of New Reactors; and (10) the completion of flooding and integrated assessment work related to lessons learned from the accident at Fukushima Dai-ichi in Japan. In addition, the total budgeted resources decreased due to the utilization of prior year unobligated carryover funding.

The 10 CFR part 170 estimated billings declined primarily due to decreases in both licensing actions and inspections resulting from the shutdown of the Pilgrim and TMI–1 reactors at the end of FY 2019; the planned shutdown of Indian Point Nuclear Generating, Unit 2 (Indian Point 2) during FY 2020; and the completion of the Advanced Power Reactor-1400 design certification, which was issued in FY 2019, for Korea Hydro and Nuclear Power Co., LTD. Additionally, estimated billings under 10 CFR part 170 are expected to decline due to the completion of the NuScale SMR design certification review and the completion of the Clinch River early site permit technical review.

The recoverable budgeted costs are divided equally among the 95 licensed operating power reactors, resulting in a

proposed annual fee of $4,534,000 per reactor. As part of the proposed annual fee, an approximate $2,442,000 current year collection adjustment was included in the operating power reactors calculation due to the planned shutdown of Indian Point 2 as shown in Table VI. Additionally, each licensed operating power reactor is assessed the FY 2020 spent fuel storage/reactor decommissioning proposed annual fee of $172,000 (see Table VII and the discussion that follows). The combined proposed FY 2020 annual fee for each operating power reactor is, therefore, $4,706,000.

In 2016, the NRC amended its licensing, inspection, and annual fee regulations to establish a variable annual fee structure for light-water SMRs (81 FR 32617). Under the variable annual fee structure, an SMR's annual fee would be calculated as a function of its licensed thermal power rating. Currently, there are no operating SMRs; therefore, the NRC is not proposing an annual fee in FY 2020 for this type of licensee.

b. Spent Fuel Storage/Reactor Decommissioning

The NRC proposes to collect $21.0 million in annual fees from 10 CFR part 50 power reactors, and from 10 CFR part 72 licensees that do not hold a 10 CFR part 50 license, to recover the budgeted costs for the spent fuel storage/reactor decommissioning fee class, as shown in Table VII. The FY 2019 fees and percentage changes are shown for comparison purposes.

TABLE VII—ANNUAL FEE SUMMARY CALCULATIONS FOR SPENT FUEL STORAGE/REACTOR DECOMMISSIONING

[Dollars in millions]

Summary fee calculations	FY 2019 final	FY 2020 proposed	Percentage change
Total budgeted resources	$35.6	$37.9	6.6
Less estimated 10 CFR part 170 receipts	−17.8	−17.8	−0.2
Net 10 CFR part 171 resources	17.8	20.2	13.4
Allocated generic transportation costs	0.7	0.8	15.7
Fee-relief adjustment	0.0	−0.1	−874.5
Billing adjustments	0.1	0.2	88.2
Total required annual fee recovery	18.6	21.0	13.2
Total spent fuel storage facilities	122	122	0.0
Annual fee per facility	$0.152	$0.172	13.2

In comparison to FY 2019, the resources budgeted for the spent fuel storage/reactor decommissioning fee class increased for reviews of new storage license renewal applications for Holtec HI-Storm 100, TN–32, TN–68, NAC UMS, NAC–MPC, Westinghouse W–150, and GE-Hitachi Morris Operation, which are expected in FY 2020; inspection activities related to site preparation for decommissioning of TMI–1, Pilgrim, Oyster Creek, and Indian Point; and fuel performance research. In addition, budgeted resources for contract costs increased due to a reduction in the utilization of prior year unobligated carryover funding compared to FY 2019.

The 10 CFR part 170 estimated billings for FY 2020 decreased due to the completion of certain follow-up inspections and enforcement activities for San Onofre Nuclear Generating Station. This decrease in the 10 CFR part 170 estimated billings is offset by increased work in the reactors-in-decommissioning program resulting from the final status reviews at multiple sites, and also due to the license transfer application for the Crystal River Nuclear Generating Plant, Unit 3.

The required annual fee recovery amount is divided equally among 122 licensees, resulting in a proposed FY 2020 annual fee of $172,000 per licensee.

c. Fuel Facilities

The NRC proposes to collect $18.1 million in annual fees from the fuel facilities fee class, as shown in Table VIII. The FY 2019 fees and percentage changes are shown for comparison purposes.

TABLE VIII—ANNUAL FEE SUMMARY CALCULATIONS FOR FUEL FACILITIES

[Dollars in millions]

Summary fee calculations	FY 2019 final	FY 2020 proposed	Percentage change
Total budgeted resources	$30.0	$23.2	−22.6
Less estimated 10 CFR part 170 receipts	−7.3	−6.8	−7.0
Net 10 CFR part 171 resources	22.7	16.5	−27.6
Allocated generic transportation	1.2	1.2	1.2
Fee-relief adjustment/LLW surcharge	0.5	0.4	−23.3
Billing adjustments	0.1	0.1	0.0
Total remaining required annual fee recovery	$24.5	$18.1	−25.9

In comparison to FY 2019, the resources budgeted for the fuel facilities fee class decreased in FY 2020. The reduction in budgetary resources is primarily due to an expected decline in submissions for license renewal applications, the decrease in the number of license amendments, the termination of the MOX Fuel Fabrication Facility

construction authorization, and efficiencies gained because of changes to the Fuel Facilities Inspection Program and workload projections. The 10 CFR part 170 estimated billings decrease as a result of the license application for the MOX Fuel Fabrication Facility being withdrawn.

The NRC proposes to continue allocating annual fees to individual fuel facility licensees based on the effort/fee determination matrix developed in the FY 1999 final fee rule (64 FR 31447; June 10, 1999). To briefly recap, the matrix groups licensees within this fee class into various fee categories. The matrix lists processes conducted at licensed sites and assigns effort factors for the safety and safeguards activities associated with each process (these effort levels are reflected in Table IX). The annual fees are then distributed across the fee class based on the regulatory effort assigned by the matrix. The effort factors in the matrix represent regulatory effort that is not recovered through 10 CFR part 170 fees (*e.g.,* rulemaking, guidance). Regulatory effort for activities that are subject to 10 CFR part 170 fees, such as the number of inspections, is not applicable to the effort factor.

TABLE IX—EFFORT FACTORS FOR FUEL FACILITIES, FY 2020

Facility type (fee category)	Number of facilities	Effort factors	
		Safety	Safeguards
High-Enriched Uranium Fuel (1.A.(1)(a))	2	88	91
Low-Enriched Uranium Fuel (1.A.(1)(b))	3	70	21
Limited Operations (1.A.(2)(a))	0	0	0
Gas Centrifuge Enrichment Demonstration (1.A.(2)(b))	0	0	0
Hot Cell (and others) (1.A.(2)(c))	0	0	0
Uranium Enrichment (1.E.)	1	16	23
UF_6 Conversion and Deconversion (2.A.(1))	1	12	7

In FY 2020, the total remaining amount of annual fees to be recovered, $18.1 million, is comprised of safety activities, safeguards activities, and the fee-relief adjustment/LLW surcharge. For FY 2020, the total budgeted resources to be recovered as annual fees for safety activities are $10.0 million. To calculate the annual fee, the NRC allocates this amount to each fee category based on its percentage of the total regulatory effort for safety activities. Similarly, the NRC allocates the budgeted resources to be recovered as annual fees for safeguards activities, $7.7 million, to each fee category based on its percentage of the total regulatory effort for safeguards activities. Finally, the fuel facilities fee class portion of the fee-relief adjustment/LLW surcharge—$0.4 million—is allocated to each fee category based on its percentage of the total regulatory effort for both safety and safeguards activities. The annual fee per licensee is then calculated by dividing the total allocated budgeted resources for the fee category by the number of licensees in that fee category. The fee and percentage change for each facility is summarized in Table X.

TABLE X—ANNUAL FEES FOR FUEL FACILITIES

[Actual dollars]

Facility type (fee category)	FY 2019 final annual fee	FY 2020 proposed annual fee	Percentage change
High-Enriched Uranium Fuel (1.A.(1)(a))	$6,675,000	$4,944,000	−25.9
Low-Enriched Uranium Fuel (1.A.(1)(b))	2,262,000	1,675,000	−26.0
Gas Centrifuge Enrichment Demonstration (1.A.(2)(b))	N/A	N/A	N/A
Hot Cell (and others) (1.A.(2)(c))	N/A	N/A	N/A
Uranium Enrichment (1.E.)	2,909,000	2,154,000	−26.0
UF_6 Conversion and Deconversion (2.A.(1))	1,417,000	1,049,000	−26.0

d. Uranium Recovery Facilities

The NRC proposes to collect $0.2 million in annual fees from the uranium recovery facilities fee class, which is stable compared to FY 2019, as shown in Table XI. The FY 2019 fees and percentage changes are shown for comparison purposes.

TABLE XI—ANNUAL FEE SUMMARY CALCULATIONS FOR URANIUM RECOVERY FACILITIES

[Dollars in millions]

Summary fee calculations	FY 2019 final	FY 2020 proposed	Percentage change
Total budgeted resources	$1.0	$0.6	−36.6
Less estimated 10 CFR part 170 receipts	−0.8	−0.5	−44.3
Net 10 CFR part 171 resources	0.2	0.2	0.0
Allocated generic transportation	N/A	N/A	N/A
Fee-relief adjustment	0.0	0.0	0.0
Billing adjustments	0.0	0.0	0.0

TABLE XI—ANNUAL FEE SUMMARY CALCULATIONS FOR URANIUM RECOVERY FACILITIES—Continued

[Dollars in millions]

Summary fee calculations	FY 2019 final	FY 2020 proposed	Percentage change
Total required annual fee recovery	$0.2	$0.2	0.0

In comparison to FY 2019, the budgeted resources and 10 CFR part 170 estimated billings for the uranium recovery fee class decreased due to the expected reduction in support for adjudicatory actions, the uncertainty associated with the construction of the NuFuels Crownpoint site, and Cameco's announcement to cease U.S. uranium recovery operations. Budgeted resources also decreased to include additional uranium recovery resources in the fee-relief category, ''*In Situ* leach rulemaking and unregistered general licenses,'' in order to ensure the equitability and the stability of annual fees.

The NRC regulates DOE's Title I and Title II activities under Uranium Mill Tailings Radiation Control Act (UMTRCA) [3] and the proposed annual fee to DOE includes the costs specifically budgeted for the NRC's UMTRCA Title I and II activities, as well as 10 percent of the remaining budgeted costs for this fee class. The DOE's UMTRCA annual fee decreased compared to FY 2019 due to an increase in the 10 CFR part 170 estimated billings for processing groundwater corrective action plans site reviews, the anticipated workload increase at various DOE UMTRCA sites, and the fee-relief credit. The NRC assesses the remaining 90 percent of its budgeted costs to the remaining licensee in this fee class, as described in the work papers. This is reflected in Table XII as follows:

TABLE XII—COSTS RECOVERED THROUGH ANNUAL FEES; URANIUM RECOVERY FEE CLASS

[Actual dollars]

Summary of costs	FY 2019 final annual fee	FY 2020 proposed annual fee	Percentage change
DOE Annual Fee Amount (UMTRCA Title I and Title II) General Licenses:			
UMTRCA Title I and Title II budgeted costs less 10 CFR part 170 receipts	$115,888	$113,377	−2.2
10 percent of generic/other uranium recovery budgeted costs	5,431	5,612	3.3
10 percent of uranium recovery fee-relief adjustment	33	−149	−551.5
Total Annual Fee Amount for DOE (rounded)	121,000	119,000	−1.7
Annual Fee Amount for Other Uranium Recovery Licenses:.			
90 percent of generic/other uranium recovery budgeted costs less the amounts specifically budgeted for UMTRCA Title I and Title II activities	48,880	50,510	3.3
90 percent of uranium recovery fee-relief adjustment	294	−1,344	−557.1
Total Annual Fee Amount for Other Uranium Recovery Licenses	$49,173	$49,165	0.0

Further, for any non-DOE licensees, the NRC proposes to continue using a matrix to determine the effort levels associated with conducting generic regulatory actions for the different licensees in the uranium recovery fee class; this is similar to the NRC's approach for fuel facilities, described previously. The matrix methodology for uranium recovery licensees first identifies the licensee categories included within this fee class (excluding DOE). These categories are: Conventional uranium mills and heap leach facilities, uranium *in situ* recovery (ISR) and resin ISR facilities, mill tailings disposal facilities, and uranium water treatment facilities. The matrix identifies the types of operating activities that support and benefit these licensees, along with each activity's relative weight (for more information, see the work papers). Currently, there is only one remaining non-DOE licensee which is a Basic *In Situ* Recovery facility. Table XIII displays the benefit factors for the non-DOE licensee in that fee category:

TABLE XIII—BENEFIT FACTORS FOR URANIUM RECOVERY LICENSES

Fee category	Number of licensees	Benefit factor per licensee	Total value	Benefit factor percent total
Conventional and Heap Leach mills (2.A.(2)(a))	0	0	0	0
Basic *In Situ* Recovery facilities (2.A.(2)(b))	1	190	190	100.0
Expanded *In Situ* Recovery facilities (2.A.(2)(c))	0	0	0	0
Section 11e.(2) disposal incidental to existing tailings sites (2.A.(4))	0	0	0	0

[3] The Congress established the two programs, Title I and Title II, under UMTRCA to protect the public and the environment from hazards associated with uranium milling. The UMTRCA Title I program is for remedial action at abandoned mill tailings sites where tailings resulted largely from production of uranium for weapons programs. The NRC also regulates DOE's UMTRCA Title II program, which is directed toward uranium mill sites licensed by the NRC or Agreement States in or after 1978.

TABLE XIII—BENEFIT FACTORS FOR URANIUM RECOVERY LICENSES—Continued

Fee category	Number of licensees	Benefit factor per licensee	Total value	Benefit factor percent total
Total	1	190	190	100.0

The annual fee for the remaining non-DOE licensee is calculated by allocating 100 percent of the budgeted resources, as summarized in Table XIV.

TABLE XIV—ANNUAL FEES FOR URANIUM RECOVERY LICENSEES

(Other than DOE)

[Actual dollars]

Facility type (fee category)	FY 2019 final annual fee	FY 2020 proposed annual fee	Percentage change
Conventional and Heap Leach mills (2.A.(2)(a))	N/A	N/A	N/A
Basic *In Situ* Recovery facilities (2.A.(2)(b))	$49,200	$49,200	0.0
Expanded *In Situ* Recovery facilities (2.A.(2)(c))	N/A	N/A	N/A
Section 11e.(2) disposal incidental to existing tailings sites (2.A.(4))	N/A	N/A	N/A
Uranium water treatment (2.A.(5))	N/A	N/A	N/A

e. Research and Test Reactors (Non-Power Reactors)

The NRC proposes to collect $0.317 million in annual fees from the research and test reactor licensee class, as shown in Table XV. The FY 2019 fees and percentage changes are shown for comparison purposes.

TABLE XV—ANNUAL FEE SUMMARY CALCULATIONS FOR RESEARCH AND TEST REACTORS

[Actual dollars]

Summary fee calculations	FY 2019 final	FY 2020 proposed	Percentage change
Total budgeted resources	$834,280	$3,650,008	337.5
Less estimated 10 CFR part 170 receipts	−538,000	−3,370,000	526.4
Net 10 CFR part 171 resources	296,280	280,008	−5.5
Allocated generic transportation	30,971	31,356	1.2
Fee-relief adjustment	284	−8,756	−3,183.1
Billing adjustments	1,901	14,263	650.9
Total required annual fee recovery	329,436	316,871	−3.8
Total research and test reactors	4	4	0.0
Total annual fee per reactor	$82,400	$79,200	−3.9

In comparison to FY 2019, the budgeted resources for the research and test reactors increased primarily within the medical isotope production facilities due to the submittal of the SHINE Medical Technologies, Inc. (SHINE) operating license application.

The 10 CFR part 170 estimated billings also increased due to the following: (1) The submittal of SHINE's operating license application for a medical production facility; (2) the review of Aerotest Operations, Inc.'s request to amend its operating license to possession only; and (3) reviews of the National Institute of Standards and Technology and GE-Hitachi Nuclear Energy America's, LLC Nuclear Test Reactor license amendments for security plan reviews.

The proposed annual fee-recovery amount is divided equally among the four research and test reactors subject to annual fees and results in an FY 2020 annual fee of $79,200 for each licensee.

f. Rare Earth

The NRC has not allocated any budgeted resources to this fee class; therefore, the NRC is not proposing an annual fee for this fee class in FY 2020.

g. Materials Users

The NRC proposes to collect $34.1 million in annual fees from materials users licensed under 10 CFR parts 30, 40, and 70, as shown in Table XVI. The FY 2019 fees and percentage changes are shown for comparison purposes.

TABLE XVI—ANNUAL FEE SUMMARY CALCULATIONS FOR MATERIALS USERS

[Dollars in millions]

Summary fee calculations	FY 2019 final	FY 2020 proposed	Percentage change
Total budgeted resources for licensees not regulated by Agreement States	$36.0	$33.7	−6.4
Less estimated 10 CFR part 170 receipts	−1.1	1.1	1.0
Net 10 CFR part 171 resources	35.0	32.7	−6.6
Allocated generic transportation	1.2	1.3	5.3
Fee-relief adjustment/LLW surcharge	0.1	0.0	−64.5
Billing adjustments	0.1	0.1	65.4
Total required annual fee recovery	$36.4	$34.1	−6.3

The annual fee for these categories of materials users' licenses is developed as follows: Annual Fee = Constant × [Application Fee + (Average Inspection Cost/Inspection Priority)] + Inspection Multiplier × (Average Inspection Cost/Inspection Priority) + Unique Category Costs.

The total annual fee recovery of $34.1 million proposed for FY 2020 shown in Table XVI consists of $26.5 million for general costs and $7.5 million for inspection costs. To equitably and fairly allocate the $34.1 million required to be collected among approximately 2,600 diverse materials users licensees, the NRC continues to calculate the annual fees for each fee category within this class based on the 10 CFR part 170 application fees and estimated inspection costs for each fee category. Because the application fees and inspection costs are indicative of the complexity of the materials license, this approach provides a proxy for allocating the generic and other regulatory costs to the diverse fee categories. This fee-calculation method also considers the inspection frequency (priority), which is indicative of the safety risk and resulting regulatory costs associated with the categories of licenses.

The NRC proposes to decrease annual fees for licensees in this fee class in FY 2020 due to the utilization of prior year unobligated carryover funding and reductions of regional resources for the Nuclear Regulatory Apprenticeship Network (formerly the Nuclear Safety Professional Development Program), and budget estimates that are better aligned with projected workload. In addition, there was a reduction of materials users licensees from FY 2019. The materials users fee class increased the number of Certificates of Compliance (CoCs) from 25 to 26, which increased the percentage of transportation resources that benefit the fee class.

The constant multiplier is established to recover the total general costs (including allocated generic transportation costs) of $26.5 million. To derive the constant multiplier, the general cost amount is divided by the product of all fee categories (application fee plus the inspection fee divided by inspection priority) then multiplied by the number of licensees. This calculation results in a constant multiplier of 1.27 for FY 2020. The average inspection cost is the average inspection hours for each fee category multiplied by the professional hourly rate of $279. The inspection priority is the interval between routine inspections, expressed in years. The inspection multiplier is established in order to recover the $7.5 million in inspection costs. To derive the inspection multiplier, the inspection costs amount is divided by the product of all fee categories (inspection fee divided by inspection priority) then multiplied by the number of licensees. This calculation results in an inspection multiplier of 1.48 for FY 2020. The unique category costs are any special costs that the NRC has budgeted for a specific category of licenses. Please see the work papers for more detail about this classification.

The annual fee assessed to each licensee also takes into account a share of the approximately $0.065 million fee-relief credit assessment allocated to the materials users fee class (see Table IV, ''Allocation of Fee-Relief Adjustment and LLW Surcharge, FY 2019,'' in Section IV, ''Discussion,'' of this document), and for certain categories of these licensees, a share of the approximately $0.113 million LLW surcharge costs allocated to the fee class. The proposed annual fee for each fee category is shown in the proposed revision to § 171.16(d).

h. Transportation

The NRC proposes to collect $1.0 million in annual fees to recover generic transportation budgeted resources in FY 2020, as shown in Table XVII. The FY 2019 fees and percentage changes are shown for comparison purposes.

TABLE XVII—ANNUAL FEE SUMMARY CALCULATIONS FOR TRANSPORTATION

[Dollars in millions]

Summary fee calculations	FY 2019 final	FY 2020 proposed	Percentage change
Total Budgeted Resources	$8.0	$7.2	−10.2
Less Estimated 10 CFR part 170 Receipts	−3.7	−2.7	−27.0
Net 10 CFR part 171 Resources	4.3	4.5	4.6
Less Generic Transportation Resources	−3.3	−3.5	5.7
Fee-relief adjustment/LLW surcharge	0.0	0.0	0.0
Billing adjustments	0.0	0.0	0.0
Total required annual fee recovery	$1.0	$1.0	0.6

In comparison to FY 2019, the total budgeted resources for generic transportation activities decreased due to the utilization of prior year unobligated carryover funding, a reduction in FTE due to decreases in maintenance work associated with the Storage and Transportation Information Management System, and the decline in DOE's percentage of total CoCs as a result of three new CoCs benefitting other fee classes. The 10 CFR part 170 estimated billings decreased primarily due to the issuance of CoCs for NAC International, Inc. and Industrial Nuclear Company, LLC in FY 2019.

Consistent with the policy established in the NRC's FY 2006 final fee rule (71 FR 30721; May 30, 2006), the NRC recovers generic transportation costs unrelated to DOE by including those costs in the annual fees for licensee fee classes. The NRC continues to assess a separate annual fee under § 171.16, fee category 18.A., for DOE transportation activities. The amount of the allocated generic resources is calculated by multiplying the percentage of total CoCs used by each fee class (and DOE) by the total generic transportation resources to be recovered.

This resource distribution to the licensee fee classes and DOE is shown in Table XVIII. Note that for the research and test reactors fee class, the NRC allocates the distribution to only those licensees that are subject to annual fees. Although four CoCs benefit the entire research and test reactor class, only 4 out of 31 research and test reactors are subject to annual fees. Consequently, the number of CoCs used to determine the proportion of generic transportation resources allocated annual fees for the research and test reactors fee class has been adjusted to 0.7 so these licensees are charged a fair and equitable portion of the total fees. For more information, see the work papers.

TABLE XVIII—DISTRIBUTION OF TRANSPORTATION RESOURCES, FY 2020

[Dollars in millions]

Licensee fee class/DOE	Number of CoCs benefiting fee class or DOE	Percentage of total CoCs	Allocated generic transportation resources
Materials Users	26.0	28.1	1.3
Operating Power Reactors	5.0	5.4	0.2
Spent Fuel Storage/Reactor Decommissioning	16.0	17.3	0.8
Research and Test Reactors	0.7	0.7	0.0
Fuel Facilities	24.0	25.9	1.2
Sub-Total of Generic Transportation Resources	71.7	77.3	3.5
DOE	21.0	22.7	1.0
Total	92.7	100.0	4.5

The NRC assesses an annual fee to DOE based on the 10 CFR part 71 CoCs it holds. The NRC, therefore, does not allocate these DOE-related resources to other licensees' annual fees because these resources specifically support DOE.

FY 2020—Policy Changes

The NRC proposes two policy changes for FY 2020:

Remove the Fee Exceptions in § 170.21, Footnote 1 and § 170.31, Footnote 2

The NRC proposes to eliminate the fee exceptions set forth in footnote 1 to § 170.21 ''Schedule of Fees for Production and Utilization Facilities, Review of Standard Referenced Design Approvals, Special Projects, Inspections, and Import and Export Licenses,'' and footnote 2 to § 170.31, ''Schedule of Fees for Materials Licenses and Other Regulatory Services, Including Inspections, and Import and Export Licenses.'' These footnotes contain parallel language stating that the NRC ''will not charge fees under 10 CFR part 170 for orders related to civil penalties or other civil sanctions issued by the Commission under § 2.202 or for amendments resulting specifically from the requirements of these orders.''

Currently, the language in footnote 1 to § 170.21 and footnote 2 to § 170.31 is an exception to the general rule that the NRC recovers review and inspection costs through fees assessed to individuals under 10 CFR part 170. The current language excludes the following activities from 10 CFR part 170 fees if an order relates to a civil penalty or other sanction: (1) Subsequent NRC inspection or review work to ensure compliance with the terms of the order, and (2) subsequent NRC review costs if the order requires the licensee to seek a license amendment. The current language also states, however, that where an order is ''unrelated to civil penalties or other civil sanctions,'' the NRC will follow its normal practice of assessing fees under 10 CFR part 170.

The language in these footnotes comes from the NRC's FY 2005 fee rule (70 FR 30526; May 26, 2005). Before 2005, the NRC excluded work in connection with *all* orders from 10 CFR part 170 fees. In the FY 2005 fee rule, the NRC amended the footnotes to narrow the exceptions to just those orders that ''relate'' to civil penalties or civil sanctions. The NRC made this change because, after September 11, 2001, it had imposed additional security requirements on multiple licensees through orders. As a result of these orders, the NRC performed extensive follow-up activities that, because of the pre-existing broad exceptions in footnotes 1 and 2, were exempt from 10 CFR part 170 fees. Because the NRC's activities were exempt from 10 CFR part 170 fees, the NRC recovered the associated costs through annual fees under 10 CFR part 171, even though the work benefited specific licensees (70 FR 30528–30535; May 26, 2005).

Through the FY 2005 fee rule, the NRC attempted to more fairly allocate costs by ensuring that the beneficiaries of its review and inspection services associated with orders of the type issued after September 11, 2001, paid for those services through 10 CFR part 170 fees. At the same time, the NRC retained an exception for orders that relate to a civil penalty or civil sanction. The NRC also explained in the FY 2005 fee rule that it was maintaining its longstanding policy of not charging 10 CFR part 170 fees for the *preparation* of any order. The costs associated with preparing an

order would continue to be recovered through annual fees under 10 CFR part 171.

The authority for assessing the 10 CFR part 171 fees comes from the same statute that provides the authority for the NRC's 10 CFR part 170 fee schedule. That statute—the IOAA—requires that the NRC assess fees fairly and equitably, and it authorizes the NRC to collect fees whenever the agency provides ''a service or thing of value'' to a recipient. In addition, OBRA–90 and Office of Management and Budget (OMB) Circular A–25, ''User Charges,'' require that the NRC recover fees from persons who derive a special benefit from the agency's services.

Even if an order related to a civil penalty or civil sanction has some public benefit, the services the NRC provides in connection with the order, such as inspections and document-review activities, primarily benefit the licensee. These services primarily benefit the licensee because they enable the licensee to maintain its NRC license in good standing and continue operating its facility. Furthermore, regardless of whether the NRC issues an order in a safety, security, or enforcement context, the NRC's follow-up services related to the order—inspections, document review and analysis, and other services—benefit the licensee by contributing to public confidence in the safe operation of the licensee's facility. Charging 10 CFR part 170 fees for services related to all orders is therefore most consistent with the NRC's obligations under the IOAA, OBRA–90, and OMB Circular A–25. Transferring the cost of these services to other members of a licensee's fee class, on the other hand, could therefore be viewed as unfair and inconsistent with the IOAA, OBRA–90, and Circular A–25.

Accordingly, in this proposed rule, the NRC proposes removing the fee exceptions (*i.e.,* the first two sentences) from § 170.21, footnote 1 and § 170.31, footnote 2. Removing the exceptions will promote fairness and equity in the NRC's fees rules, consistent with the IOAA; and it will help ensure that licensees who receive special benefits in the form of NRC services pay for those services, consistent with OMB Circular A–25. Removing the exceptions will also simplify the NRC's fee rules. If there are circumstances in which charging 10 CFR part 170 fees for follow-up activities related to an order would be unfair, the NRC retains the ability under 10 CFR 170.11 to grant a fee exemption for those services, either on its own initiative or upon request.

Removing the fee exceptions will not, however, change the NRC's longstanding policy regarding the recovery of costs associated with preparing an order. Consistent with this policy, such costs will continue to be recovered through annual fees under 10 CFR part 171.

Amending § 171.15 Regarding the Assessment of Annual Fees for 10 CFR Part 52 Combined License Holders and Future 10 CFR Part 50 Power Reactor Licensees

Based on its review of PRM–171–1 and the public comments, the NRC proposes to amend § 171.15(a) so that the assessment of annual fees for 10 CFR part 52 COL holders commences upon successful completion of power ascension testing, rather than after the Commission makes a finding under § 52.103(g) finding. The NRC is also proposing to apply this approach to future 10 CFR part 50 power reactor licensees.

Currently, § 171.15 requires a 10 CFR part 52 COL holder to begin paying the annual fee once the Commission finds under § 52.103(g) that all acceptance criteria in the COL are met. Similarly, 10 CFR part 50 licensees begin paying annual fees upon issuance of an operating license. The timing of annual fees reflects the NRC's historical position that a nuclear power reactor licensee receives the benefits of its license, and thus should begin paying annual fees, when the NRC authorizes the licensee to use nuclear materials (*i.e.,* begin operating the reactor).

As stated in its fee rules, the NRC is firmly committed to the application of fairness and equity in the assessment of fees to licensees. The NRC recognizes that, subsequent to the § 52.103(g) finding for 10 CFR part 52 COL holders, and issuance of the operating license for 10 CFR part 50 power reactor licensees, fuel must be loaded, and power ascension testing must be completed to provide assurance that the facility is fully operational. As part of this process, 10 CFR part 52 COL holders must provide written notification to the NRC that successful power ascension testing is completed. This notification is the trigger that enables operation at a steady-state reactor core power level equal to 100 percent of reactor thermal power as defined in the facility's final safety analysis report.

As a result, the NRC recognizes that it would be fairer and more equitable to change the timing of when annual fees commence for 10 CFR part 52 licensees from when the Commission issues a § 52.103(g) finding to a time that aligns more closely with the licensee's facility becoming fully operational. For that reason, the NRC is proposing to defer charging annual fees until after the licensee's start-up and initial-testing phase. The NRC proposes to begin charging annual fees only after the licensee has notified the NRC in writing that it has successfully completed power ascension testing. For similar reasons, the NRC also proposes to apply this change to 10 CFR part 50 power reactor licensees.

Because only current 10 CFR part 52 COLs contain a standard license condition that requires written notification be submitted to the NRC upon successful completion of power ascension testing, the NRC will consider adding a similar license condition to future 10 CFR part 50 operating licenses and 10 CFR part 52 COLs to ensure that they promptly notify the NRC of successful completion of power ascension testing. Upon successful completion of testing and the required notification to the NRC, the power reactor would be fully operational. The annual fee assessment for 10 CFR part 50 power reactor licensees and 10 CFR part 52 COL holders would therefore begin on the date of the licensee's written notification of successful completion of power ascension testing.

Accordingly, the NRC proposes to amend § 171.15(a) so that annual fees commence not upon issuance of the operating license for 10 CFR part 50 power reactors and issuance of the § 52.103(g) finding for 10 CFR part 52 COL holders, but upon written notification to the NRC of successful completion of power ascension testing. The NRC finds that this proposal would be a reasonable, fair, and equitable revision of the NRC's fee rule. The public comments the NRC received on PRM–171–1 were supportive of this type of proposed change. Among the commenters were NEI, which represents numerous members of the class of licensees that would be directly impacted by this change. Because of this proposed policy change, the NRC also proposes to make conforming changes to revise § 171.3, ''Scope,'' and § 171.17, ''Proration.'' Finally, the NRC will consider expanding the scope of this approach to apply to other 10 CFR part 50 licensees in a future rulemaking.

FY 2020—Administrative Change

The NRC also proposes to make one administrative change:

Add a footnote to the table in § 171.16(d) for additional clarity.

The NRC is proposing to add a footnote to the table in 10 CFR 171.16(d) to clarify that licensees that are subject to annual fees under fee categories 4.A., 4.B. or 4.C. are not subject to fees under

3.N. for waste disposal services authorized on the same license.

Update on the Fees Transformation Initiative

In the Staff Requirements Memorandum, dated October 19, 2016, (ADAMS Accession No. ML16293A902) for SECY–16–0097, ''Fee Setting Improvements and Fiscal Year 2017 Proposed Fee Rule,'' (ADAMS Accession No. ML16194A365), the Commission directed staff to explore, as a voluntary pilot, whether the NRC could establish a flat fee structure for routine licensing matters in the area of uranium recovery, and to accelerate the process improvements for setting fees, including the transition to an electronic billing system. In addition, the Commission also directed the staff to begin the fees transformation activities listed in SECY–16–0097 as ''Process Changes Recommended for Future Consideration—FY 2018 and Beyond,'' which includes one remaining item to complete regarding the rulemaking to update the NRC's small business size standards in 10 CFR 2.810, ''NRC Size Standards.''

With respect to the uranium recovery flat fee pilot initiative, the NRC explored the feasibility of establishing a flat fee structure for routine licensing matters and inspection activities. The NRC provided a report to Congress on January 9, 2020, describing the results of the pilot initiative and the decision to maintain the current NRC fee billing structure for 10 CFR part 170 fees for service for uranium recovery licensing matters. For more information, the report to Congress can be found at ADAMS Accession No. ML20010D684.

With respect to the NRC's transition to an electronic billing system (eBilling), eBilling went live with a phased implementation on October 1, 2019, for 9 licensees with 65 dockets. Other licensees will be phased in throughout the year. The NRC is targeting October 2020 as the month when full implementation will take place.

Finally, in order to obtain sufficient information to update the NRC's small business size standard in 10 CFR 2.810, the NRC is conducting a financial survey of materials licensees to determine whether changes to the size standards are needed. The NRC published a notice in the **Federal Register** (85 FR 6225; February 4, 2020) announcing the survey, with a requested due date of April 30, 2020, to complete the survey in order to achieve a high response rate. Licensees may submit a response to the survey electronically through the internet. This survey can be accessed, and responses entered, on the NRC public website at *www.NRC.gov.* At the bottom of the first screen under the section titled, ABOUT US, click on LICENSE FEES. Next screen, click in the box titled RELATED INFORMATION, click on the item Small Entity Classification Survey. Proceed to complete the survey. In addition, licensees were mailed a paper survey with an NRC-addressed, business reply return envelop included in the mailing, which can be submitted through the U.S. mail in lieu of responding to the survey electronical. The survey results will be used to acquire the data needed to determine if changes are needed, and the impact of changing the current nuclear industry-specific standards.

For more information, please see our fees transformation accomplishments schedule, located on our license fees website at: *https://www.nrc.gov/about-nrc/regulatory/licensing/fees-transformation-accomplishments.html.*

V. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, as amended (RFA),[4] the NRC has prepared a regulatory flexibility analysis related to this proposed rule. The regulatory flexibility analysis is available as indicated in Section XIV, Availability of Documents, of this document.

VI. Regulatory Analysis

Under OBRA–90, the NRC is required to recover approximately 90 percent of its budget authority in FY 2020. The NRC established fee methodology guidelines for 10 CFR part 170 in 1978, and established additional fee methodology guidelines for 10 CFR part 171 in 1986. In subsequent rulemakings, the NRC has adjusted its fees without changing the underlying principles of its fee policy to ensure that the NRC continues to comply with the statutory requirements for cost recovery in OBRA–90.

In this proposed rule, the NRC continues this longstanding approach. Therefore, the NRC did not identify any alternatives to the current fee structure guidelines and did not prepare a regulatory analysis for this proposed rule.

VII. Backfitting and Issue Finality

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule and that a backfit analysis is not required. A backfit analysis is not required because these amendments do not require the modification of, or addition to, systems, structures, components, or the design of a facility, or the design approval or manufacturing license for a facility, or the procedures or organization required to design, construct, or operate a facility.

VIII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act, as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885). The NRC requests comment on the proposed rule with respect to the clarity and effectiveness of the language used.

IX. National Environmental Policy Act

The rule is limited to amending the NRC's administrative requirements in 10 CFR parts 170 and 171. Therefore, this action is categorically excluded from needing environmental review, as described in § 51.22(c)(1). Consequently, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed rule.

X. Paperwork Reduction Act

This proposed rule does not contain a collection of information as defined in the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XI. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC proposes to amend the licensing, inspection, and annual fees charged to its licensees and applicants, as necessary, to recover approximately 90 percent of its budget authority in FY 2020, as required by OBRA–90. This action does not constitute the establishment of a standard that

[4] 5 U.S.C. 603. The RFA, 5 U.S.C. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, Title II, 110 Stat. 847 (1996).

contains generally applicable requirements.

XII. Availability of Guidance

The Small Business Regulatory Enforcement Fairness Act requires all Federal agencies to prepare a written compliance guide for each rule for which the agency is required by 5 U.S.C. 604 to prepare a regulatory flexibility analysis. The NRC, in compliance with the law, prepared the ''Small Entity Compliance Guide'' for the FY 2019 proposed fee rule. The NRC plans to continue to use this compliance guide for FY 2020 and has relabeled the compliance guide to reflect the current fiscal year. The FY 2020 version of the compliance guide is available as indicated in Section XIV, Availability of Documents, of this document. The next compliance guide will be developed when the NRC completes the next small entity biennial review in FY 2021.

XIII. Public Meeting

The NRC will conduct a public meeting for the purpose of describing this proposed rule and answering questions from the public on this proposed rule. The NRC will publish a notice of the location, time, and agenda of the meeting on the NRC's public meeting website within at least 10 calendar days before the meeting. In addition, the agenda for the meeting will be posted on *www.regulations.gov* under Docket ID NRC–2017–0228. For instructions to receive alerts when changes or additions occur in a docket folder, see Section XIV, Availability of Documents, of this document. Stakeholders should monitor the NRC's public meeting website for information about the public meeting at: *https://www.nrc.gov/public-involve/public-meetings/index.cfm.*

XIV. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Documents	ADAMS Accession No./Web Link
SECY–05–0164, ''Annual Fee Calculation Method,'' dated September 15, 2005.	ML052580332.
SECY–16–0097, ''Fee Setting Improvements and Fiscal Year 2017 Proposed Fee Rule,'' dated August 15, 2016.	ML16194A365.
Staff Requirements Memorandum for SECY–16–0097, dated October 19, 2016.	ML16293A902.
NUREG–1100, Volume 35, ''Congressional Budget Justification: Fiscal Year 2020'' (February 2019).	ML19065A279.
Petition for Rulemaking–171–1, ''Petition to Amend 10 CFR 171.15, ''Reactor Licenses and Independent Spent Fuel Storage Licenses,'' dated February 28, 2019.	ML19081A015.
''Nuclear Power Plant License Fees Upon Commencing Commercial Operation,'' partial consideration in the rulemaking process (84 FR 65032; November 26, 2019).	*https://www.govinfo.gov/content/pkg/FR-2019-11-26/html/2019-25581.htm.*
FY 2020 Proposed Rule Work Papers	ML19343A735.
''Uranium Recovery Flat Fee Pilot Initiative: A Report for the Senate Committee on Environment and Public Works and the House Committee on Energy and Commerce''.	ML20010D684.
FY 2020 Proposed Fee Rule	ML19312B014.
FY 2020 Regulatory Flexibility Analysis	ML19318G030.
FY 2020 U.S. Nuclear Regulatory Commission Small Entity Compliance Guide.	ML19318G044.
NRC Form 526, ''Certification of Small Entity Status for the Purposes of Annual Fees Imposed under 10 CFR Part 171''.	*https://www.nrc.gov/reading-rm/doc-collections/forms/nrc526.pdf.*
OMB Circular A–25, ''User Charges''	*https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/circulars/a025/a025.html.*
Fees Transformation Accomplishments	https://www.nrc.gov/about-nrc/regulatory/licensing/fees-transformation-accomplishments.html.
Small Entity Classification Survey	*https://forms.office.com/Pages/ResponsePage.aspx?id=dRTQ6LXDakOgZV3vTGT1LokV9jkSmnJMh_vCoMlesDBUNUxHN0JSMkdDTlc0TzhMUUxKV_ktaRVVWVSQlQCN0PWcu.*

Throughout the development of this rule, the NRC may post documents related to this rule, including public comments, on the Federal Rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2017–0228. The Federal Rulemaking website allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder NRC–2017–0228; (2) click the ''Sign up for Email Alerts'' link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

List of Subjects

10 CFR Part 170

Byproduct material, Import and export licenses, Intergovernmental relations, Non-payment penalties, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

10 CFR Part 171

Annual charges, Approvals, Byproduct material, Holders of certificates, Intergovernmental relations, Nonpayment penalties, Nuclear materials, Nuclear power plants and reactors, Registrations, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is proposing to adopt the following amendments to 10 CFR parts 170 and 171:

PART 170—FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES, AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

■ 1. The authority citation for part 170 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 161(w) (42 U.S.C. 2014, 2201(w)); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 42 U.S.C. 2214; 31 U.S.C. 901, 902, 9701; 44 U.S.C. 3504 note.

§ 170.20 [Amended]

■ 2. In § 170.20, remove the dollar amount ''$275'' and add in its place the dollar amount ''$279''.

■ 3. In § 170.21, revise the entry for ''K. Import and export licenses'' and footnotes 1 and 6 to read as follows:

§ 170.21 Schedule of fees for production and utilization facilities, review of standard referenced design approvals, special projects, inspections and import and export licenses.

* * * * *

SCHEDULE OF FACILITY FEES

[See footnotes at end of table]

Facility categories and type of fees	Fees [1] [2]
* * * * * * *	
K. Import and export licenses: [6]	
Licenses for the import and export only of production or utilization facilities or the export only of components for production or utilization facilities issued under 10 CFR part 110.	
1. Application for import or export of production or utilization facilities [4] (including reactors and other facilities) and exports of components requiring Commission and Executive Branch review, for example, actions under 10 CFR 110.40(b).	
Application—new license, or amendment; or license exemption request	N/A.
2. Application for export of reactor and other components requiring Executive Branch review, for example, those actions under 10 CFR 110.41(a).	
Application—new license, or amendment; or license exemption request	N/A
3. Application for export of components requiring the assistance of the Executive Branch to obtain foreign government assurances.	
Application—new license, or amendment; or license exemption request	N/A
4. Application for export of facility components and equipment not requiring Commission or Executive Branch review, or obtaining foreign government assurances.	
Application—new license, or amendment; or license exemption request	N/A
5. Minor amendment of any active export or import license, for example, to extend the expiration date, change domestic information, or make other revisions which do not involve any substantive changes to license terms or conditions or to the type of facility or component authorized for export and, therefore, do not require in-depth analysis or review or consultation with the Executive Branch, U.S. host state, or foreign government authorities.	
Minor amendment to license	N/A

[1] Fees will be charged for approvals issued under a specific exemption provision of the Commission's regulations under title 10 of the *Code of Federal Regulations* (*e.g.,* 10 CFR 50.12, 10 CFR 73.5) and any other sections in effect now or in the future, regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form.

[2] Full cost fees will be determined based on the professional staff time and appropriate contractual support services expended. For applications currently on file and for which fees are determined based on the full cost expended for the review, the professional staff hours expended for the review of the application up to the effective date of the final rule will be determined at the professional rates in effect when the service was provided.

[3] * * * * * * *

[4] Imports only of major components for end-use at NRC-licensed reactors are authorized under NRC general import license in 10 CFR 110.27.

* * * * * * *

[6] Because the Further Consolidated Appropriations Act, 2020, excludes international activities from the fee-recoverable budget in FY 2020, import and export licensing actions will not be charged fees.

■ 4. In § 170.31, revise the table to read as follows:

§ 170.31 Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses.

* * * * *

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fees [2] [3]
1. Special nuclear material: [11]	
A. (1) Licenses for possession and use of U–235 or plutonium for fuel fabrication activities.	
(a) Strategic Special Nuclear Material (High Enriched Uranium) [6] [Program Code(s): 21213]	Full Cost.
(b) Low Enriched Uranium in Dispersible Form Used for Fabrication of Power Reactor Fuel [6] [Program Code(s): 21210].	Full Cost.
(2) All other special nuclear materials licenses not included in Category 1.A. (1) which are licensed for fuel cycle activities. [6]	
(a) Facilities with limited operations [6] [Program Code(s): 21240, 21310, 21320]	Full Cost.
(b) Gas centrifuge enrichment demonstration facilities. [6] [Program Code(s): 21205]	Full Cost.
(c) Others, including hot cell facilities. [6] [Program Code(s): 21130, 21133]	Full Cost.

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fees [2 3]
B. Licenses for receipt and storage of spent fuel and reactor-related Greater than Class C (GTCC) waste at an independent spent fuel storage installation (ISFSI) [6] [Program Code(s): 23200]	Full Cost.
C. Licenses for possession and use of special nuclear material of less than a critical mass as defined in § 70.4 in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers.[4]	
Application [Program Code(s): 22140]	$1,300.
D. All other special nuclear material licenses, except licenses authorizing special nuclear material in sealed or unsealed form in combination that would constitute a critical mass, as defined in § 70.4 of this chapter, for which the licensee shall pay the same fees as those under Category 1.A.[4]	
Application [Program Code(s): 22110, 22111, 22120, 22131, 22136, 22150, 22151, 22161, 22170, 23100, 23300, 23310].	$2,600.
E. Licenses or certificates for construction and operation of a uranium enrichment facility [6] [Program Code(s): 21200]	Full Cost.
F. Licenses for possession and use of special nuclear material greater than critical mass as defined in § 70.4 of this chapter, for development and testing of commercial products, and other non-fuel-cycle activities.[4 6] [Program Code(s): 22155].	Full Cost.
2. Source material: [11]	
A. (1) Licenses for possession and use of source material for refining uranium mill concentrates to uranium hexafluoride or for deconverting uranium hexafluoride in the production of uranium oxides for disposal.[6] [Program Code(s): 11400].	Full Cost.
(2) Licenses for possession and use of source material in recovery operations such as milling, *in-situ* recovery, heap-leaching, ore buying stations, ion-exchange facilities, and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.[6]	
(a) Conventional and Heap Leach facilities [6] [Program Code(s): 11100]	Full Cost.
(b) Basic *In Situ* Recovery facilities [6] [Program Code(s): 11500]	Full Cost.
(c) Expanded *In Situ* Recovery facilities [6] [Program Code(s): 11510]	Full Cost.
(d) *In Situ* Recovery Resin facilities [6] [Program Code(s): 11550]	Full Cost.
(e) Resin Toll Milling facilities [6] [Program Code(s): 11555]	Full Cost.
(f) Other facilities[6] [Program Code(s): 11700]	Full Cost.
(3) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal, except those licenses subject to the fees in Category 2.A.(2) or Category 2.A.(4) [6] [Program Code(s): 11600, 12000].	Full Cost.
(4) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal incidental to the disposal of the uranium waste tailings generated by the licensee's milling operations, except those licenses subject to the fees in Category 2.A.(2) [6] [Program Code(s): 12010].	Full Cost.
B. Licenses which authorize the possession, use, and/or installation of source material for shielding.[7 8]	
Application [Program Code(s): 11210]	$1,200.
C. Licenses to distribute items containing source material to persons exempt from the licensing requirements of part 40 of this chapter.	
Application [Program Code(s): 11240]	$4,300.
D. Licenses to distribute source material to persons generally licensed under part 40 of this chapter.	
Application [Program Code(s): 11230, 11231].	$2,800.
E. Licenses for possession and use of source material for processing or manufacturing of products or materials containing source material for commercial distribution.	
Application [Program Code(s): 11710]	$2,700.
F. All other source material licenses.	
Application [Program Code(s): 11200, 11220, 11221, 11300, 11800, 11810, 11820]	$2,700.
3. Byproduct material: [11]	
A. Licenses of broad scope for the possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 1–5.	
Application [Program Code(s): 03211, 03212, 03213]	$13,100.
(1). Licenses of broad scope for the possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 6–20.	
Application [Program Code(s): 04010, 04012, 04014]	$17,400.
(2). Licenses of broad scope for the possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: more than 20.	
Application [Program Code(s): 04011, 04013, 04015]	$21,700.
B. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 1–5.	
Application [Program Code(s): 03214, 03215, 22135, 22162]	$3,600.
(1). Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 6–20.	
Application [Program Code(s): 04110, 04112, 04114, 04116]	$4,800.
(2). Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: more than 20.	
Application [Program Code(s): 04111, 04113, 04115, 04117]	$6,000.

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fees [2 3]
C. Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4). Number of locations of use: 1–5.	
Application [Program Code(s): 02500, 02511, 02513]	$5,200.
(1). Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4). Number of locations of use: 6–20.	
Application [Program Code(s): 04210, 04212, 04214]	$6,900.
(2). Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4). Number of locations of use: more than 20.	
Application [Program Code(s): 04211, 04213, 04215]	$8,700.
D. [Reserved]	N/A.
E. Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units).	
Application [Program Code(s): 03510, 03520]	$3,200.
F. Licenses for possession and use of less than or equal to 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes.	
Application [Program Code(s): 03511]	$6,500.
G. Licenses for possession and use of greater than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes.	
Application [Program Code(s): 03521]	$62,300.
H. Licenses issued under subpart A of part 32 of this chapter to distribute items containing byproduct material that require device review to persons exempt from the licensing requirements of part 30 of this chapter. The category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter.	
Application [Program Code(s): 03254, 03255, 03257]	$6,700.
I. Licenses issued under subpart A of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require device evaluation to persons exempt from the licensing requirements of part 30 of this chapter. This category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter.	
Application [Program Code(s): 03250, 03251, 03252, 03253, 03256]	$11,600.
J. Licenses issued under subpart B of part 32 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under part 31 of this chapter. This category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter.	
Application [Program Code(s): 03240, 03241, 03243]	$2,000.
K. Licenses issued under subpart B of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under part 31 of this chapter. This category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter.	
Application [Program Code(s): 03242, 03244]	$1,100.
L. Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: 1–5.	
Application [Program Code(s): 01100, 01110, 01120, 03610, 03611, 03612, 03613]	$5,500.
(1) Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: 6–20.	
Application [Program Code(s): 04610, 04612, 04614, 04616, 04618, 04620, 04622]	$7,300.
(2) Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: more than 20.	
Application [Program Code(s): 04611, 04613, 04615, 04617, 04619, 04621, 04623]	$9,100.
M. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for research and development that do not authorize commercial distribution.	
Application [Program Code(s): 03620]	$8,300.
N. Licenses that authorize services for other licensees, except:	
(1) Licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee Category 3.P.; and	
(2) Licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4.A., 4.B., and 4.C.	
Application [Program Code(s): 03219, 03225, 03226]	$8,900.
O. Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. Number of locations of use: 1–5.	
Application [Program Code(s): 03310, 03320]	$6,400.

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fees [2 3]
(1). Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. Number of locations of use: 6–20.	
Application [Program Code(s): 04310, 04312]	$8,500.
(2). Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. Number of locations of use: more than 20.	
Application [Program Code(s): 04311, 04313]	$10,600
P. All other specific byproduct material licenses, except those in Categories 4.A. through 9.D. [9] Number of locations of use: 1–5.	
Application [Program Code(s): 02400, 02410, 03120, 03121, 03122, 03123, 03124, 03130, 03140, 03220, 03221, 03222, 03800, 03810, 22130].	$4,700.
(1). All other specific byproduct material licenses, except those in Categories 4.A. through 9.D. [9] Number of locations of use: 6–20.	
Application [Program Code(s): 04410, 04412, 04414, 04416, 04418, 04420, 04422, 04424, 04426, 04428, 04430, 04432, 04434, 04436, 04438].	$6,300.
(2). All other specific byproduct material licenses, except those in Categories 4.A. through 9.D.[9] Number of locations of use: more than 20.	
Application [Program Code(s): 04411, 04413, 04415, 04417, 04419, 04421, 04423, 04425, 04427, 04429, 04431, 04433, 04435, 04437, 04439].	$7,900.
Q. Registration of a device(s) generally licensed under part 31 of this chapter.	
Registration	$600.
R. Possession of items or products containing radium-226 identified in 10 CFR 31.12 which exceed the number of items or limits specified in that section.[5]	
1. Possession of quantities exceeding the number of items or limits in 10 CFR 31.12(a)(4) or (5) but less than or equal to 10 times the number of items or limits specified.	
Application [Program Code(s): 02700]	$2,600.
2. Possession of quantities exceeding 10 times the number of items or limits specified in 10 CFR 31.12(a)(4) or (5). Application [Program Code(s): 02710].	
S. Licenses for production of accelerator-produced radionuclides.	$2,500
Application [Program Code(s): 03210]	$14,300.
4. Waste disposal and processing: [11]	
A. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material.	
Application [Program Code(s): 03231, 03233, 03236, 06100, 06101]	Full Cost.
B. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.	
Application [Program Code(s): 03234]	$6,900.
C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.	
Application [Program Code(s): 03232]	$5,000.
5. Well logging: [11]	
A. Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies.	
Application [Program Code(s): 03110, 03111, 03112]	$4,600.
B. Licenses for possession and use of byproduct material for field flooding tracer studies.	
Licensing [Program Code(s): 03113]	Full Cost.
6. Nuclear laundries: [11]	
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material.	
Application [Program Code(s): 03218]	$22,200.
7. Medical licenses: [11]	
A. Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. Number of locations of use: 1–5.	
Application [Program Code(s): 02300, 02310]	$11,200.
(1). Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. Number of locations of use: 6–20.	
Application [Program Code(s): 04510, 04512]	$14,800.
(2). Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. Number of locations of use: more than 20.	
Application [Program Code(s): 04511, 04513]	$18,500.

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fees [2 3]
B. Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. Number of locations of use: 1–5.	
Application [Program Code(s): 02110]	$8,700.
(1). Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. Number of locations of use: 6–20.	
Application [Program Code(s): 04710]	$11,600.
(2). Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. Number of locations of use: more than 20.	
Application [Program Code(s): 04711]	$14,500.
C. Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices.[10] Number of locations of use: 1–5.	
Application [Program Code(s): 02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 22160]	$6,600
(1). Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices.[10] Number of locations of use: 6–20.	
Application [Program Code(s): 04810, 04812, 04814, 04816, 04818, 04820, 04822, 04824, 04826, 04828]	$8,800.
(2). Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices.[10] Number of locations of use: more than 20.	
Application [Program Code(s): 04811,04813, 04815, 04817, 04819, 04821,04823, 04825, 04827, 04829]	$10,900.
8. Civil defense:[11]	
A. Licenses for possession and use of byproduct material, source material, or special nuclear material for civil defense activities.	
Application [Program Code(s): 03710]	$2,600.
9. Device, product, or sealed source safety evaluation:	
A. Safety evaluation of devices or products containing byproduct material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution.	
Application—each device	$10,900.
B. Safety evaluation of devices or products containing byproduct material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel devices.	
Application—each device	$9,000.
C. Safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, except reactor fuel, for commercial distribution.	
Application—each source	$5,300.
D. Safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel.	
Application—each source	$1,100.
10. Transportation of radioactive material:	
A. Evaluation of casks, packages, and shipping containers.	
1. Spent Fuel, High-Level Waste, and plutonium air packages	Full Cost.
2. Other Casks	Full Cost.
B. Quality assurance program approvals issued under part 71 of this chapter.	
1. Users and Fabricators.	
Application	$4,200.
Inspections	Full Cost.
2. Users..	
Application	$4,200.
Inspections	Full Cost.
C. Evaluation of security plans, route approvals, route surveys, and transportation security devices (including immobilization devices).	Full Cost.
11. Review of standardized spent fuel facilities.	Full Cost.
12. Special projects:	
Including approvals, pre-application/licensing activities, and inspections.	
Application [Program Code: 25110]	Full Cost.
13. A. Spent fuel storage cask Certificate of Compliance	Full Cost.
B. Inspections related to storage of spent fuel under § 72.210 of this chapter	Full Cost.
14. Decommissioning/Reclamation [11]	

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fees [2 3]
A. Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation, or site restoration activities under parts 30, 40, 70, 72, and 76 of this chapter, including master materials licenses (MMLs). The transition to this fee category occurs when a licensee has permanently ceased principal activities. [Program Code(s): 03900, 11900, 21135, 21215, 21240, 21325, 22200].	Full Cost.
B. Site-specific decommissioning activities associated with unlicensed sites, including MMLs, regardless of whether or not the sites have been previously licensed..	Full Cost.
15. Import and Export licenses: [12]	
Licenses issued under part 110 of this chapter for the import and export only of special nuclear material, source material, tritium and other byproduct material, and the export only of heavy water, or nuclear grade graphite (fee categories 15.A. through 15.E.).	
A. Application for export or import of nuclear materials, including radioactive waste requiring Commission and Executive Branch review, for example, those actions under 10 CFR 110.40(b).	
Application—new license, or amendment; or license exemption request	N/A.
B. Application for export or import of nuclear material, including radioactive waste, requiring Executive Branch review, but not Commission review. This category includes applications for the export and import of radioactive waste and requires the NRC to consult with domestic host state authorities (i.e., Low-Level Radioactive Waste Compact Commission, the U.S. Environmental Protection Agency, etc.).	
Application—new license, or amendment; or license exemption request	N/A.
C. Application for export of nuclear material, for example, routine reloads of low enriched uranium reactor fuel and/or natural uranium source material requiring the assistance of the Executive Branch to obtain foreign government assurances.	
Application—new license, or amendment; or license exemption request	N/A
D. Application for export or import of nuclear material not requiring Commission or Executive Branch review, or obtaining foreign government assurances.	
Application—new license, or amendment; or license exemption request	N/A.
E. Minor amendment of any active export or import license, for example, to extend the expiration date, change domestic information, or make other revisions which do not involve any substantive changes to license terms and conditions or to the type/quantity/chemical composition of the material authorized for export and, therefore, do not require in-depth analysis, review, or consultations with other Executive Branch, U.S. host state, or foreign government authorities.	
Minor amendment	N/A
Licenses issued under part 110 of this chapter for the import and export only of Category 1 and Category 2 quantities of radioactive material listed in appendix P to part 110 of this chapter (fee categories 15.F. through 15.R.).	
Category 1 (Appendix P, 10 CFR Part 110) Exports:	
F. Application for export of appendix P Category 1 materials requiring Commission review (e.g. exceptional circumstance review under 10 CFR 110.42(e)(4)) and to obtain one government-to-government consent for this process. For additional consent see fee category 15.I.	
Application—new license, or amendment; or license exemption request	N/A.
G. Application for export of appendix P Category 1 materials requiring Executive Branch review and to obtain one government-to-government consent for this process. For additional consents see fee category 15.I.	
Application—new license, or amendment; or license exemption request	N/A.
H. Application for export of appendix P Category 1 materials and to obtain one government-to-government consent for this process. For additional consents see fee category 15.I.	
Application—new license, or amendment; or license exemption request	N/A
I. Requests for each additional government-to-government consent in support of an export license application or active export license.	
Application—new license, or amendment; or license exemption request	N/A.
Category 2 (Appendix P, 10 CFR Part 110) Exports:	
J. Application for export of appendix P Category 2 materials requiring Commission review (e.g. exceptional circumstance review under 10 CFR 110.42(e)(4)).	
Application—new license, or amendment; or license exemption request	N/A.
K. Applications for export of appendix P Category 2 materials requiring Executive Branch review.	
Application—new license, or amendment; or license exemption request	N/A.
L. Application for the export of Category 2 materials.	
Application—new license, or amendment; or license exemption request	N/A.
M. [Reserved]	N/A.
N. [Reserved]	N/A.
O. [Reserved]	N/A.
P. [Reserved]	N/A.
Q. [Reserved]	N/A.
Minor Amendments (Category 1 and 2, Appendix P, 10 CFR Part 110, Export):	
R. Minor amendment of any active export license, for example, to extend the expiration date, change domestic information, or make other revisions which do not involve any substantive changes to license terms and conditions or to the type/quantity/chemical composition of the material authorized for export and, therefore, do not require in-depth analysis, review, or consultations with other Executive Branch, U.S. host state, or foreign authorities.	
Minor amendment	N/A.
16. Reciprocity:	
Agreement State licensees who conduct activities under the reciprocity provisions of 10 CFR 150.20.	
Application	$2,100.
17. Master materials licenses of broad scope issued to Government agencies.	
Application [Program Code(s): 03614]	Full Cost.
18. Department of Energy.	

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fees [2 3]
A. Certificates of Compliance. Evaluation of casks, packages, and shipping containers (including spent fuel, high-level waste, and other casks, and plutonium air packages)..	Full Cost.
B. Uranium Mill Tailings Radiation Control Act (UMTRCA) activities.	Full Cost.

[1] *Types of fees*—Separate charges, as shown in the schedule, will be assessed for pre-application consultations and reviews; applications for new licenses, approvals, or license terminations; possession-only licenses; issuances of new licenses and approvals; certain amendments and renewals to existing licenses and approvals; safety evaluations of sealed sources and devices; generally licensed device registrations; and certain inspections. The following guidelines apply to these charges:

(a) *Application and registration fees.* Applications for new materials licenses and export and import licenses; applications to reinstate expired, terminated, or inactive licenses, except those subject to fees assessed at full costs; applications filed by Agreement State licensees to register under the general license provisions of 10 CFR 150.20; and applications for amendments to materials licenses that would place the license in a higher fee category or add a new fee category must be accompanied by the prescribed application fee for each category.

(1) Applications for licenses covering more than one fee category of special nuclear material or source material must be accompanied by the prescribed application fee for the highest fee category.

(2) Applications for new licenses that cover both byproduct material and special nuclear material in sealed sources for use in gauging devices will pay the appropriate application fee for fee category 1.C. only.

(b) *Licensing fees.* Fees for reviews of applications for new licenses, renewals, and amendments to existing licenses, pre-application consultations and other documents submitted to the NRC for review, and project manager time for fee categories subject to full cost fees are due upon notification by the Commission in accordance with § 170.12(b).

(c) *Amendment fees.* Applications for amendments to export and import licenses must be accompanied by the prescribed amendment fee for each license affected. An application for an amendment to an export or import license or approval classified in more than one fee category must be accompanied by the prescribed amendment fee for the category affected by the amendment, unless the amendment is applicable to two or more fee categories, in which case the amendment fee for the highest fee category would apply.

(d) *Inspection fees.* Inspections resulting from investigations conducted by the Office of Investigations and nonroutine inspections that result from third-party allegations are not subject to fees. Inspection fees are due upon notification by the Commission in accordance with § 170.12(c).

(e) *Generally licensed device registrations under 10 CFR 31.5.* Submittals of registration information must be accompanied by the prescribed fee.

[2] Fees will be charged for approvals issued under a specific exemption provision of the Commission's regulations under title 10 of the *Code of Federal Regulations* (*e.g.,* 10 CFR 30.11, 40.14, 70.14, 73.5, and any other sections in effect now or in the future), regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. In addition to the fee shown, an applicant may be assessed an additional fee for sealed source and device evaluations as shown in fee categories 9.A. through 9.D.

[3] Full cost fees will be determined based on the professional staff time multiplied by the appropriate professional hourly rate established in § 170.20 in effect when the service is provided, and the appropriate contractual support services expended.

[4] Licensees paying fees under categories 1.A., 1.B., and 1.E. are not subject to fees under categories 1.C., 1.D. and 1.F. for sealed sources authorized in the same license, except for an application that deals only with the sealed sources authorized by the license.

[5] Persons who possess radium sources that are used for operational purposes in another fee category are not also subject to the fees in this category. (This exception does not apply if the radium sources are possessed for storage only.)

[6] Licensees subject to fees under fee categories 1.A., 1.B., 1.E., or 2.A. must pay the largest applicable fee and are not subject to additional fees listed in this table.

[7] Licensees paying fees under 3.C., 3.C.1, or 3.C.2 are not subject to fees under 2.B. for possession and shielding authorized on the same license.

[8] Licensees paying fees under 7.C. are not subject to fees under 2.B. for possession and shielding authorized on the same license.

[9] Licensees paying fees under 3.N. are not subject to paying fees under 3.P., 3.P.1, or 3.P.2 for calibration or leak testing services authorized on the same license.

[10] Licensees paying fees under 7.B., 7.B.1, or 7.B.2 are not subject to paying fees under 7.C., 7.C.1, or 7.C.2. for broad scope licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices authorized on the same license.

[11] A materials license (or part of a materials license) that transitions to fee category 14.A is assessed full-cost fees under 10 CFR part 170, but is not assessed an annual fee under 10 CFR part 171. If only part of a materials license is transitioned to fee category 14.A, the licensee may be charged annual fees (and any applicable 10 CFR part 170 fees) for other activities authorized under the license that are not in decommissioning status.

[12] Because the Further Consolidated Appropriations Act, 2020, excludes international activities from the fee-recoverable budget in FY 2020, import and export licensing actions will not be charged fees.

PART 171—ANNUAL FEES FOR REACTOR LICENSES AND FUEL CYCLE LICENSES AND MATERIALS LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS AND GOVERNMENT AGENCIES LICENSED BY THE NRC

■ 5. The authority citation for part 171 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 161(w), 223, 234 (42 U.S.C. 2014, 2201(w), 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 42 U.S.C. 2214; 44 U.S.C. 3504 note.

■ 6. Revise § 171.3 to read as follows:

§ 171.3 Scope.

The regulations in this part apply to any person holding an operating license for a test reactor or research reactor issued under part 50 of this chapter, and to any person holding an operating license for a power reactor licensed under 10 CFR part 50 or a combined license issued under 10 CFR part 52 that has provided notification to the NRC that the licensee has successfully completed power ascension testing. The regulations in this part also apply to any person holding a materials license as defined in this part, a Certificate of Compliance, a sealed source or device registration, a quality assurance program approval, and to a Government agency as defined in this part. Notwithstanding the other provisions in this section, the regulations in this part do not apply to uranium recovery and fuel facility licensees until after the Commission verifies through inspection that the facility has been constructed in accordance with the requirements of the license.

■ 7. In § 171.15, revise paragraphs (a), (b)(1) and (2) introductory text, (c)(1) and (2) introductory text, (d)(1) introductory text, (d)(2) and (3), and (f) to read as follows:

§ 171.15 Annual fees: Reactor licenses and independent spent fuel storage licenses.

(a) Each person holding an operating license for a test or research reactor; each person holding an operating license for a power reactor licensed under 10 CFR part 50 or a combined license under 10 CFR part 52 that has provided notification to the NRC that the licensee has successfully completed power ascension testing; each person holding a 10 CFR part 50 or 10 CFR part 52 power reactor license that is in decommissioning or possession only status, except those that have no spent fuel onsite; and each person holding a 10 CFR part 72 license who does not hold a 10 CFR part 50 or 10 CFR part 52 license and provides notification in accordance with 10 CFR 72.80(g), shall pay the annual fee for each license held during the Federal fiscal year in which the fee is due. This paragraph (a) does not apply to test or research reactors exempted under § 171.11(b).

(b)(1) The FY 2020 annual fee for each operating power reactor that must be collected by September 30, 2020, is $4,534,000.

(2) The FY 2020 annual fees are comprised of a base annual fee for power reactors licensed to operate, a base spent fuel storage/reactor decommissioning annual fee, and associated additional charges (fee-relief adjustment). The activities comprising the spent fuel storage/reactor decommissioning base annual fee are shown in paragraphs (c)(2)(i) and (ii) of this section. The activities comprising the FY 2020 fee-relief adjustment are shown in paragraph (d)(1) of this section. The activities comprising the FY 2020 base annual fee for operating power reactors are as follows:

* * * * *

(c)(1) The FY 2020 annual fee for each power reactor holding a 10 CFR part 50 license or combined license issued under 10 CFR part 52 that is in a decommissioning or possession-only status and has spent fuel onsite, and for each independent spent fuel storage 10 CFR part 72 licensee who does not hold a 10 CFR part 50 license or a 10 CFR part 52 combined license, is $172,000.

(2) The FY 2020 annual fee is comprised of a base spent fuel storage/reactor decommissioning annual fee (which is also included in the operating power reactor annual fee shown in paragraph (b) of this section) and a fee-relief adjustment. The activities comprising the FY 2020 fee-relief adjustment are shown in paragraph (d)(1) of this section. The activities comprising the FY 2020 spent fuel storage/reactor decommissioning rebaselined annual fee are:

* * * * *

(d)(1) The fee-relief adjustment allocated to annual fees includes a surcharge for the activities listed in paragraph (d)(1)(i) of this section, plus the amount remaining after total budgeted resources for the activities included in paragraphs (d)(1)(ii) and (iii) of this section are reduced by the appropriations the NRC receives for these types of activities. If the NRC's appropriations for these types of activities are greater than the budgeted resources for the activities included in paragraphs (d)(1)(ii) and (iii) of this section for a given fiscal year, annual fees will be reduced. The activities comprising the FY 2020 fee-relief adjustment are as follows:

* * * * *

(2) The total FY 2020 fee-relief adjustment allocated to the operating power reactor class of licenses is a $1,484,630 fee-relief credit, not including the amount allocated to the spent fuel storage/reactor decommissioning class. The FY 2020 operating power reactor fee-relief adjustment to be assessed to each operating power reactor is approximately a $15,628 fee-relief credit. This amount is calculated by dividing the total operating power reactor fee-relief credit, $1,484,630, by the number of operating power reactors (95).

(3) The FY 2020 fee-relief adjustment allocated to the spent fuel storage/reactor decommissioning class of licenses is a $92,071 fee-relief credit. The FY 2020 spent fuel storage/reactor decommissioning fee relief adjustment to be assessed to each operating power reactor, each power reactor in decommissioning or possession-only status that has spent fuel onsite, and to each independent spent fuel storage 10 CFR part 72 licensee who does not hold a 10 CFR part 50 license, is a $755 fee-relief credit. This amount is calculated by dividing the total fee-relief credit by the total number of power reactors licenses, except those that permanently ceased operations and have no fuel onsite, and 10 CFR part 72 licensees who do not hold a 10 CFR part 50 license.

* * * * *

(f) The FY 2020 annual fees for licensees authorized to operate a research or test (non-power) reactor licensed under 10 CFR part 50, unless the reactor is exempted from fees under § 171.11(a), are as follows:

TABLE 2 TO PARAGRAPH (f)

Research reactor	$79,200
Test reactor	79,200

■ 8. In § 171.16, revise paragraphs (c), (d), and (e) introductory text to read as follows:

§ 171.16 Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC.

* * * * *

(c) A licensee who is required to pay an annual fee under this section, in addition to 10 CFR part 72 licenses, may qualify as a small entity. If a licensee qualifies as a small entity and provides the Commission with the proper certification along with its annual fee payment, the licensee may pay reduced annual fees as shown in table 1 to this paragraph (c). Failure to file a small entity certification in a timely manner could result in the receipt of a delinquent invoice requesting the outstanding balance due and/or denial of any refund that might otherwise be due. The small entity fees are as follows:

TABLE 1 TO PARAGRAPH (c)

NRC small entity classification	Maximum annual fee per licensed category
Small Businesses Not Engaged in Manufacturing (Average gross receipts over last 3 completed fiscal years):	
$485,000 to $7 million	$4,500
Less than $485,000	900
Small Not-For-Profit Organizations (Annual Gross Receipts):	
$485,000 to $7 million	4,500

TABLE 1 TO PARAGRAPH (c)—Continued

NRC small entity classification	Maximum annual fee per licensed category
Less than $485,000	900
Manufacturing Entities that Have An Average of 500 Employees or Fewer:	
35 to 500 employees	4,500
Fewer than 35 employees	900
Small Governmental Jurisdictions (Including publicly supported educational institutions) (Population):	
20,000 to 49,999	4,500
Fewer than 20,000	900
Educational Institutions that are not State or Publicly Supported, and have 500 Employees or Fewer	
35 to 500 employees	4,500
Fewer than 35 employees	900

(d) The FY 2020 annual fees are comprised of a base annual fee and an allocation for fee-relief adjustment. The activities comprising the FY 2020 fee-relief adjustment are shown for convenience in paragraph (e) of this section. The FY 2020 annual fees for materials licensees and holders of certificates, registrations, or approvals subject to fees under this section are shown in table 2 to this paragraph (d):

TABLE 2 TO PARAGRAPH (d)—SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC

[See footnotes at end of table]

Category of materials licenses	Annual fees [1 2 3]
1. Special nuclear material:	
A. (1) Licenses for possession and use of U–235 or plutonium for fuel fabrication activities.	
(a) Strategic Special Nuclear Material (High Enriched Uranium)[15] [Program Code(s): 21130]	$4,944,000
(b) Low Enriched Uranium in Dispersible Form Used for Fabrication of Power Reactor Fuel [15] [Program Code(s): 21210]	$1,675,000
(2) All other special nuclear materials licenses not included in Category 1.A.(1) which are licensed for fuel cycle activities.	
(a) Facilities with limited operations [15] [Program Code(s): 21310, 21320]	N/A
(b) Gas centrifuge enrichment demonstration facility [15]	N/A
(c) Others, including hot cell facility [15]	N/A
B. Licenses for receipt and storage of spent fuel and reactor-related Greater than Class C (GTCC) waste at an independent spent fuel storage installation (ISFSI) [11 15] [Program Code(s): 23200]	N/A
C. Licenses for possession and use of special nuclear material of less than a critical mass, as defined in § 70.4 of this chapter, in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers. [Program Code(s): 22140]	$2,800
D. All other special nuclear material licenses, except licenses authorizing special nuclear material in sealed or unsealed form in combination that would constitute a critical mass, as defined in § 70.4 of this chapter, for which the licensee shall pay the same fees as those under Category 1.A. [Program Code(s): 22110, 22111, 22120, 22131, 22136, 22150, 22151, 22161, 22170, 23100, 23300, 23310]	$7,100
E. Licenses or certificates for the operation of a uranium enrichment facility [15] [Program Code(s): 21200]	$2,154,000
F. Licenses for possession and use of special nuclear materials greater than critical mass, as defined in § 70.4 of this chapter, for development and testing of commercial products, and other non-fuel cycle activities.[4] [Program Code: 22155]	$5,100
2. Source material:	
A. (1) Licenses for possession and use of source material for refining uranium mill concentrates to uranium hexafluoride or for deconverting uranium hexafluoride in the production of uranium oxides for disposal.[15] [Program Code: 11400]	$1,049,000
(2) Licenses for possession and use of source material in recovery operations such as milling, in-situ recovery, heap-leaching, ore buying stations, ion-exchange facilities and in-processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.	
(a) Conventional and Heap Leach facilities.[15] [Program Code(s): 11100]	N/A
(b) Basic *In Situ* Recovery facilities.[15] [Program Code(s): 11500]	$49,200
(c) Expanded *In Situ* Recovery facilities[15] [Program Code(s): 11510]	N/A
(d) *In Situ* Recovery Resin facilities.[15] [Program Code(s): 11550]	[5] N/A
(e) Resin Toll Milling facilities.[15] [Program Code(s): 11555]	[5] N/A
(3) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal, except those licenses subject to the fees in Category 2.A.(2) or Category 2.A.(4).[15] [Program Code(s): 11600, 12000]	[5] N/A
(4) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal incidental to the disposal of the uranium waste tailings generated by the licensee's milling operations, except those licenses subject to the fees in Category 2.A.(2).[15] [Program Code(s): 12010]	N/A
B. Licenses which authorize the possession, use, and/or installation of source material for shielding.[16 17] Application [Program Code(s): 11210]	$3,100

TABLE 2 TO PARAGRAPH (d)—SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees [1 2 3]
C. Licenses to distribute items containing source material to persons exempt from the licensing requirements of part 40 of this chapter. [Program Code: 11240]	$7,700
D. Licenses to distribute source material to persons generally licensed under part 40 of this chapter. [Program Code(s): 11230 and 11231]	$6,000
E. Licenses for possession and use of source material for processing or manufacturing of products or materials containing source material for commercial distribution. [Program Code: 11710]	$7,500
F. All other source material licenses. [Program Code(s): 11200, 11220, 11221, 11300, 11800, 11810, 11820]	$9,200
3. Byproduct material:	
A. Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 1–5. [Program Code(s): 03211, 03212, 03213]	$28,000
(1). Licenses of broad scope for the possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 6–20. [Program Code(s): 03211, 03212, 03213]	$37,100
(2). Licenses of broad scope for the possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: more than 20. [Program Code(s): 04011, 04013, 04015]	$46,300
B. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 1–5. [Program Code(s): 03214, 03215, 22135, 22162]	$11,400
(1). Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 6–20. [Program Code(s): 04110, 04112, 04114, 04116]	$15,000
(2). Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: more than 20. [Program Code(s): 04111, 04113, 04115, 04117]	$18,700
C. Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4). Number of locations of use: 1–5. [Program Code(s): 02500, 02511, 02513]	$10,500
(1). Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4). Number of locations of use: 6–20. [Program Code(s): 04210, 04212, 04214]	$13,900
(2). Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4). Number of locations of use: more than 20. [Program Code(s): 04211, 04213, 04215]	$17,400
D. [Reserved]	[5] N/A
E. Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units). [Program Code(s): 03510, 03520]	$11,700
F. Licenses for possession and use of less than or equal to 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes. [Program Code(s): 03511]	$10,700
G. Licenses for possession and use of greater than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes. [Program Code(s): 03521]	$85,100
H. Licenses issued under subpart A of part 32 of this chapter to distribute items containing byproduct material that require device review to persons exempt from the licensing requirements of part 30 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter. [Program Code(s): 03254, 03255, 03257]	$10,600
I. Licenses issued under subpart A of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require device evaluation to persons exempt from the licensing requirements of part 30 of this chapter, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter. [Program Code(s): 03250, 03251, 03252, 03253, 03256]	$16,900
J. Licenses issued under subpart B of part 32 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter. [Program Code(s): 03240, 03241, 03243]	$4,100
K. Licenses issued under subpart B of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter. [Program Code(s): 03242, 03244]	$3,000

TABLE 2 TO PARAGRAPH (d)—SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees [1 2 3]
L. Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: 1–5. [Program Code(s): 01100, 01110, 01120, 03610, 03611, 03612, 03613]	$15,000
(1) Licenses of broad scope for possession and use of product material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: 6–20. [Program Code(s): 04610, 04612, 04614, 04616, 04618, 04620, 04622]	$19,800
(2) Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: more than 20. [Program Code(s): 04611, 04613, 04615, 04617, 04619, 04621, 04623]	$24,700
M. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for research and development that do not authorize commercial distribution. [Program Code(s): 03620]	$14,400
N. Licenses that authorize services for other licensees, except: (1) Licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee Category 3.P.; and (2) Licenses that authorize waste disposal services are subject to the fees specified in fee categories 4.A., 4.B., and 4.C.[21] [Program Code(s): 03219, 03225, 03226]	$18,100
O. Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. This category also includes the possession and use of source material for shielding authorized under part 40 of this chapter when authorized on the same license Number of locations of use: 1–5. [Program Code(s): 03310, 03320]	$29,800
(1). Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. This category also includes the possession and use of source material for shielding authorized under part 40 of this chapter when authorized on the same license. Number of locations of use: 6–20. [Program Code(s): 04310, 04312]	$39,900
(2). Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. This category also includes the possession and use of source material for shielding authorized under part 40 of this chapter when authorized on the same license. Number of locations of use: more than 20. [Program Code(s): 04311, 04313]	$49,700
P. All other specific byproduct material licenses, except those in Categories 4.A. through 9.D.[18] Number of locations of use: 1–5. [Program Code(s): 02400, 02410, 03120, 03121, 03122, 03123, 03124, 03140, 03130, 03220, 03221, 03222, 03800, 03810, 22130]	$9,700
(1). All other specific byproduct material licenses, except those in Categories 4.A. through 9.D.[18] Number of locations of use: 6–20. [Program Code(s): 04410, 04412, 04414, 04416, 04418, 04420, 04422, 04424, 04426, 04428, 04430, 04432, 04434, 04436, 04438]	$13,000
(2). All other specific byproduct material licenses, except those in Categories 4.A. through 9.D.[18] Number of locations of use: more than 20. [Program Code(s): 04411, 04413, 04415, 04417, 04419, 04421, 04423, 04425, 04427, 04429, 04431, 04433, 04435, 04437, 04439]	$16,300
Q. Registration of devices generally licensed under part 31 of this chapter	[13]N/A
R. Possession of items or products containing radium–226 identified in 10 CFR 31.12 which exceed the number of items or limits specified in that section: [14]	
(1). Possession of quantities exceeding the number of items or limits in 10 CFR 31.12(a)(4), or (5) but less than or equal to 10 times the number of items or limits specified. [Program Code(s): 02700]	$7,000
(2). Possession of quantities exceeding 10 times the number of items or limits specified in 10 CFR 31.12(a)(4) or (5). [Program Code(s): 02710]	$7,300
S. Licenses for production of accelerator-produced radionuclides. [Program Code(s): 03210]	$30,200
4. Waste disposal and processing:	
A. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material. [Program Code(s): 03231, 03233, 03235, 03236, 06100, 06101]	$31,900
B. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material. [Program Code(s): 03234]	$18,100
C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material. [Program Code(s): 03232]	$10,300
5. Well logging:	
A. Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies. [Program Code(s): 03110, 03111, 03112]	$14,300
B. Licenses for possession and use of byproduct material for field flooding tracer studies. [Program Code(s): 03113]	[5]N/A
6. Nuclear laundries:	
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material. [Program Code(s): 03218]	$34,000
7. Medical licenses:	
A. Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9] Number of locations of use: 1–5. [Program Code(s): 02300, 02310]	$25,300

TABLE 2 TO PARAGRAPH (d)—SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees [1 2 3]
(1). Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9] Number of locations of use: 6–20. [Program Code(s): 04510, 04512]	$33,500
(2). Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9] Number of locations of use: more than 20. [Program Code(s): 04511, 04513]	$42,000
B. Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9] Number of locations of use: 1–5. [Program Code(s): 02110]	$30,800
(1). Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9] Number of locations of use: 6–20. [Program Code(s): 04710]	$41,100
(2). Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9] Number of locations of use: more than 20. [Program Code(s): 04711]	$51,200
C. Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9 19] Number of locations of use: 1-5. [Program Code(s): 02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 22160]	$14,800
(1). Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9 19] Number of locations of use: 6–20. [Program Code(s): 04810, 04812, 04814, 04816, 04818, 04820, 04822, 04824, 04826, 04828]	$19,700
(2). Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9 19] Number of locations of use: more than 20. [Program Code(s): 04811, 04813, 04815, 04817, 04819, 04821, 04823, 04825, 04827, 04829]	$24,500
8. Civil defense:	
A. Licenses for possession and use of byproduct material, source material, or special nuclear material for civil defense activities. [Program Code(s): 03710]	$7,000
9. Device, product, or sealed source safety evaluation:	
A. Registrations issued for the safety evaluation of devices or products containing byproduct material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution	$13,800
B. Registrations issued for the safety evaluation of devices or products containing byproduct material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel devices	$11,400
C. Registrations issued for the safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, except reactor fuel, for commercial distribution	$6,700
D. Registrations issued for the safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel	$1,400
10. Transportation of radioactive material:	
A. Certificates of Compliance or other package approvals issued for design of casks, packages, and shipping containers.	
1. Spent Fuel, High-Level Waste, and plutonium air packages	[6] N/A
2. Other Casks	[6] N/A
B. Quality assurance program approvals issued under part 71 of this chapter.	
1. Users and Fabricators	[6] N/A
2. Users	[6] N/A
C. Evaluation of security plans, route approvals, route surveys, and transportation security devices (including immobilization devices)	[6] N/A
11. Standardized spent fuel facilities	[6] N/A
12. Special Projects. [Program Code(s): 25110]	[6] N/A
13. A. Spent fuel storage cask Certificate of Compliance	[6] N/A
B. General licenses for storage of spent fuel under 10 CFR 72.210	[12] N/A
14. Decommissioning/Reclamation:	

TABLE 2 TO PARAGRAPH (d)—SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees [1 2 3]
A. Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation, or site restoration activities under parts 30, 40, 70, 72, and 76 of this chapter, including master materials licenses (MMLs). The transition to this fee category occurs when a licensee has permanently ceased principal activities. [Program Code(s): 03900, 11900, 21135, 21215, 21240, 21325, 22200]	[7 20] N/A
B. Site-specific decommissioning activities associated with unlicensed sites, including MMLs, whether or not the sites have been previously licensed	[7] N/A
15. Import and Export licenses	[8] N/A
16. Reciprocity	[8] N/A
17. Master materials licenses of broad scope issued to Government agencies.[15] [Program Code(s): 03614]	$312,000
18. Department of Energy:	
A. Certificates of Compliance	[10] $1,026,000
B. Uranium Mill Tailings Radiation Control Act (UMTRCA) activities	$119,000

[1] Annual fees will be assessed based on whether a licensee held a valid license with the NRC authorizing possession and use of radioactive material during the current FY. The annual fee is waived for those materials licenses and holders of certificates, registrations, and approvals who either filed for termination of their licenses or approvals or filed for possession only/storage licenses before October 1 of the current FY, and permanently ceased licensed activities entirely before this date. Annual fees for licensees who filed for termination of a license, downgrade of a license, or for a possession-only license during the FY and for new licenses issued during the FY will be prorated in accordance with the provisions of § 171.17. If a person holds more than one license, certificate, registration, or approval, the annual fee(s) will be assessed for each license, certificate, registration, or approval held by that person. For licenses that authorize more than one activity on a single license (*e.g.,* human use and irradiator activities), annual fees will be assessed for each category applicable to the license.

[2] Payment of the prescribed annual fee does not automatically renew the license, certificate, registration, or approval for which the fee is paid. Renewal applications must be filed in accordance with the requirements of parts 30, 40, 70, 71, 72, or 76 of this chapter.

[3] Each FY, fees for these materials licenses will be calculated and assessed in accordance with § 171.13 and will be published in the FEDERAL REGISTER for notice and comment.

[4] Other facilities include licenses for extraction of metals, heavy metals, and rare earths.

[5] There are no existing NRC licenses in these fee categories. If NRC issues a license for these categories, the Commission will consider establishing an annual fee for this type of license.

[6] Standardized spent fuel facilities, 10 CFR parts 71 and 72 Certificates of Compliance and related Quality Assurance program approvals, and special reviews, such as topical reports, are not assessed an annual fee because the generic costs of regulating these activities are primarily attributable to users of the designs, certificates, and topical reports.

[7] Licensees in this category are not assessed an annual fee because they are charged an annual fee in other categories while they are licensed to operate.

[8] No annual fee is charged because it is not practical to administer due to the relatively short life or temporary nature of the license.

[9] Separate annual fees will not be assessed for pacemaker licenses issued to medical institutions that also hold nuclear medicine licenses under fee categories 7.A, 7.A.1, 7.A.2, 7.B., 7.B.1, 7.B.2, 7.C, 7.C.1, or 7.C.2.

[10] This includes Certificates of Compliance issued to the U.S. Department of Energy that are not funded from the Nuclear Waste Fund.

[11] See § 171.15(c).

[12] See § 171.15(c).

[13] No annual fee is charged for this category because the cost of the general license registration program applicable to licenses in this category will be recovered through 10 CFR part 170 fees.

[14] Persons who possess radium sources that are used for operational purposes in another fee category are not also subject to the fees in this category. (This exception does not apply if the radium sources are possessed for storage only.)

[15] Licensees subject to fees under categories 1.A., 1.B., 1.E., 2.A., and licensees paying fees under fee category 17 must pay the largest applicable fee and are not subject to additional fees listed in this table.

[16] Licensees paying fees under 3.C. are not subject to fees under 2.B. for possession and shielding authorized on the same license.

[17] Licensees paying fees under 7.C. are not subject to fees under 2.B. for possession and shielding authorized on the same license.

[18] Licensees paying fees under 3.N. are not subject to paying fees under 3.P., 3.P.1, or 3.P.2 for calibration or leak testing services authorized on the same license.

[19] Licensees paying fees under 7.B., 7.B.1, or 7.B.2 are not subject to paying fees under 7.C., 7.C.1, or 7.C.2 for broad scope license licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices authorized on the same license.

[20] No annual fee is charged for a materials license (or part of a materials license) that has transitioned to this fee category because the decommissioning costs will be recovered through 10 CFR part 170 fees, but annual fees may be charged for other activities authorized under the license that are not in decommissioning status.

[21] Licensees paying fees under 4.A., 4.B. or 4.C. are not subject to paying fees under 3.N. licenses that authorize services for other licensees authorized on the same license.

(e) The fee-relief adjustment allocated to annual fees includes the budgeted resources for the activities listed in paragraph (e)(1) of this section, plus the total budgeted resources for the activities included in paragraphs (e)(2) and (3) of this section, as reduced by the appropriations the NRC receives for these types of activities. If the NRC's appropriations for these types of activities are greater than the budgeted resources for the activities included in paragraphs (e)(2) and (3) of this section for a given fiscal year, a negative fee-relief adjustment (or annual fee reduction) will be allocated to annual fees. The activities comprising the FY 2020 fee-relief adjustment are as follows:

* * * * *

■ 9. In § 171.17, revise paragraphs (a) introductory text and (a)(1) and (2) to read as follows:

§ 171.17 Proration.

* * * * *

(a) Reactors, 10 CFR part 72 licensees who do not hold 10 CFR part 50 or 10 CFR part 52 licenses, and materials licenses with annual fees of $100,000 or greater for a single fee category. The NRC will base the proration of annual fees for terminated and downgraded licenses on the fee rule in effect at the time the action is official. The NRC will base the determinations on the proration

requirements under paragraphs (a)(2) and (3) of this section.

(1) *New licenses.* (i) The annual fees for new licenses for power reactors that are subject to fees under this part, for which the licensee has notified the NRC on or after October 1 of a fiscal year (FY) that the licensee has successfully completed power ascension testing, are prorated on the basis of the number of days remaining in the FY. Thereafter, the full annual fee is due and payable each subsequent FY.

(ii) The annual fees for new licenses for non-power reactors, 10 CFR part 72 licensees who do not hold 10 CFR part 50 or 10 CFR part 52 licenses, and materials licenses with annual fees of $100,000 or greater for a single fee category for the current FY, that are subject to fees under this part and are granted a license to operate on or after October 1 of a FY, are prorated on the basis of the number of days remaining in the FY. Thereafter, the full annual fee is due and payable each subsequent FY.

(2) *Terminations.* The base operating power reactor annual fee for operating reactor licensees who have requested amendment to withdraw operating authority permanently during the FY will be prorated based on the number of days during the FY the license was in effect before docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor vessel or when a final legally effective order to permanently cease operations has come into effect. The spent fuel storage/reactor decommissioning annual fee for reactor licensees who permanently cease operations and have permanently removed fuel from the site during the FY will be prorated on the basis of the number of days remaining in the FY after docketing of both the certifications of permanent cessation of operations and permanent removal of fuel from the site. The spent fuel storage/reactor decommissioning annual fee will be prorated for those 10 CFR part 72 licensees who do not hold a 10 CFR part 50 or 10 CFR part 52 license who request termination of the 10 CFR part 72 license and permanently cease activities authorized by the license during the FY based on the number of days the license was in effect before receipt of the termination request. The annual fee for materials licenses with annual fees of $100,000 or greater for a single fee category for the current FY will be prorated based on the number of days remaining in the FY when a termination request or a request for a possession-only license is received by the NRC, provided the licensee permanently ceased licensed activities during the specified period.

* * * * *

Dated at Rockville, Maryland, this 4th day of February, 2020.

For the Nuclear Regulatory Commission.

L. Benedict Ficks,

Acting Chief Financial Officer.

[FR Doc. 2020–03054 Filed 2–14–20; 8:45 am]

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FEDERAL REGISTER

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No. 32 February 18, 2020

Part V

The President

Executive Order 13905—Strengthening National Resilience Through Responsible Use of Positioning, Navigation, and Timing Services

Federal Register
Vol. 85, No. 32
Tuesday, February 18, 2020

Presidential Documents

Title 3—

The President

Executive Order 13905 of February 12, 2020

Strengthening National Resilience Through Responsible Use of Positioning, Navigation, and Timing Services

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Purpose.* The national and economic security of the United States depends on the reliable and efficient functioning of critical infrastructure. Since the United States made the Global Positioning System available worldwide, positioning, navigation, and timing (PNT) services provided by space-based systems have become a largely invisible utility for technology and infrastructure, including the electrical power grid, communications infrastructure and mobile devices, all modes of transportation, precision agriculture, weather forecasting, and emergency response. Because of the widespread adoption of PNT services, the disruption or manipulation of these services has the potential to adversely affect the national and economic security of the United States. To strengthen national resilience, the Federal Government must foster the responsible use of PNT services by critical infrastructure owners and operators.

Sec. 2. *Definitions.* As used in this order:

(a) ''PNT services'' means any system, network, or capability that provides a reference to calculate or augment the calculation of longitude, latitude, altitude, or transmission of time or frequency data, or any combination thereof.

(b) ''Responsible use of PNT services'' means the deliberate, risk-informed use of PNT services, including their acquisition, integration, and deployment, such that disruption or manipulation of PNT services minimally affects national security, the economy, public health, and the critical functions of the Federal Government.

(c) ''Critical infrastructure'' means systems and assets, whether physical or virtual, so vital to the United States that the incapacity or destruction of such systems and assets would have a debilitating impact on national security, national economic security, national public health or safety, or on any combination of those matters.

(d) ''PNT profile'' means a description of the responsible use of PNT services—aligned to standards, guidelines, and sector-specific requirements—selected for a particular system to address the potential disruption or manipulation of PNT services.

(e) ''Sector-Specific Agency'' (SSA) is the executive department or agency that is responsible for providing institutional knowledge and specialized expertise as well as leading, facilitating, or supporting the security and resilience programs and associated activities of its designated critical infrastructure sector in the all-hazards environment. The SSAs are those identified in Presidential Policy Directive 21 of February 12, 2013 (Critical Infrastructure Security and Resilience).

Sec. 3. *Policy.* It is the policy of the United States to ensure that disruption or manipulation of PNT services does not undermine the reliable and efficient functioning of its critical infrastructure. The Federal Government must increase the Nation's awareness of the extent to which critical infrastructure depends on, or is enhanced by, PNT services, and it must ensure critical infrastructure can withstand disruption or manipulation of PNT services.

To this end, the Federal Government shall engage the public and private sectors to identify and promote the responsible use of PNT services.

Sec. 4. *Implementation.* (a) Within 1 year of the date of this order, the Secretary of Commerce, in coordination with the heads of SSAs and in consultation, as appropriate, with the private sector, shall develop and make available, to at least the appropriate agencies and private sector users, PNT profiles. The PNT profiles will enable the public and private sectors to identify systems, networks, and assets dependent on PNT services; identify appropriate PNT services; detect the disruption and manipulation of PNT services; and manage the associated risks to the systems, networks, and assets dependent on PNT services. Once made available, the PNT profiles shall be reviewed every 2 years and, as necessary, updated.

(b) The Secretary of Defense, Secretary of Transportation, and Secretary of Homeland Security shall refer to the PNT profiles created pursuant to subsection (a) of this section in updates to the Federal Radionavigation Plan.

(c) Within 1 year of the date of this order, the Secretary of Homeland Security, in coordination with the heads of SSAs, shall develop a plan to test the vulnerabilities of critical infrastructure systems, networks, and assets in the event of disruption and manipulation of PNT services. The results of the tests carried out under that plan shall be used to inform updates to the PNT profiles identified in subsection (a) of this section.

(d) Within 90 days of the PNT profiles being made available, the heads of SSAs and the heads of other executive departments and agencies (agencies), as appropriate, through the Secretary of Homeland Security, shall develop contractual language for inclusion of the relevant information from the PNT profiles in the requirements for Federal contracts for products, systems, and services that integrate or utilize PNT services, with the goal of encouraging the private sector to use additional PNT services and develop new robust and secure PNT services. The heads of SSAs and the heads of other agencies, as appropriate, shall update the requirements as necessary.

(e) Within 180 days of the completion of any of the duties described in subsection (d) of this section, and consistent with applicable law and to the maximum extent practicable, the Federal Acquisition Regulatory Council, in consultation with the heads of SSAs and the heads of other agencies, as appropriate, shall incorporate the requirements developed under subsection (d) of this section into Federal contracts for products, systems, and services that integrate or use PNT services.

(f) Within 1 year of the PNT profiles being made available, and biennially thereafter, the heads of SSAs and the heads of other agencies, as appropriate, through the Secretary of Homeland Security, shall submit a report to the Assistant to the President for National Security Affairs and the Director of the Office of Science and Technology Policy (OSTP) on the extent to which the PNT profiles have been adopted in their respective agencies' acquisitions and, to the extent possible, the extent to which PNT profiles have been adopted by owners and operators of critical infrastructure.

(g) Within 180 days of the date of this order, the Secretary of Transportation, Secretary of Energy, and Secretary of Homeland Security shall each develop plans to engage with critical infrastructure owners or operators to evaluate the responsible use of PNT services. Each pilot program shall be completed within 1 year of developing the plan, and the results shall be used to inform the development of the relevant PNT profile and research and development (R&D) opportunities.

(h) Within 1 year of the date of this order, the Director of OSTP shall coordinate the development of a national plan, which shall be informed by existing initiatives, for the R&D and pilot testing of additional, robust, and secure PNT services that are not dependent on global navigation satellite systems (GNSS). The plan shall also include approaches to integrate and use multiple PNT services to enhance the resilience of critical infrastructure.

Once the plan is published, the Director of OSTP shall coordinate updates to the plan every 4 years, or as appropriate.

(i) Within 180 days of the date of this order, the Secretary of Commerce shall make available a GNSS-independent source of Coordinated Universal Time, to support the needs of critical infrastructure owners and operators, for the public and private sectors to access.

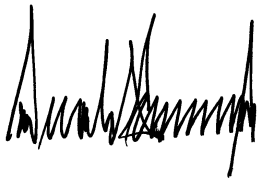
Sec. 5. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
February 12, 2020.

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655 6131
660 6135
665 7521
679 6890

LIST OF PUBLIC LAWS

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